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**Life After Treatment for Prostate Cancer:  
Levels of Anxiety, Depression, and Sexual Dysfunction  
and Research Portfolio**

**Part One (Part Two bound separately)**

Rebecca Clifford BSc  
University of Glasgow  
Section of Psychological Medicine

**August 2007**

Submitted in partial fulfilment of the requirements of the degree of Doctorate in  
Clinical Psychology

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## **Acknowledgements**

Firstly, I would like to thank Professor Keith Millar for all of his advice and support with my research portfolio.

Secondly, my project would not have been possible without the participation of the men with prostate cancer, and the help and enthusiasm of Dr Martin Russell, Edi Stewart, Fiona Muirhead and John McCoid - thank you to you all.

Finally, to my family and friends. Thank you to my parents for always supporting me in everything that I do. Thank you to Jonathan for always being there. Thank you to my study group for listening and offering advice throughout the course.

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## **Chapter 1: Small Scale Service Related Project**

### **An Audit of the Evening Clinics running in the East Area of Glasgow Clinical Psychology Service: A Management Report**

**Prepared in accordance with guidelines for 'in-service publication' in Doctorate  
of Clinical Psychology Research Training Folder**

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## Introduction

Two evening clinics were run as part of a waiting list initiative in the east area of Glasgow Clinical Psychology service. The first clinic ran from October 2002 to March 2003, the second ran from September 2003 to January 2004. A third evening clinic is planned for 2005, funding is currently being negotiated.

Improving waiting times is a key priority for the NHS in Scotland (Jones, 2003).

The subject of waiting times in the NHS has been an important issue for a number of years. The most recent work in this area has been reviewing waiting lists, and looking at more effective ways of managing them (Scottish Executive, 2003; Audit Scotland, 2002).

A review of waiting lists in Scotland said that 'waiting lists and waiting times are important measures of how the health service is responding to demand. They highlight where there are delays in particular parts of the health system' (Audit Scotland, 2002. Page 14). The review looked at: the arrangements for placing patients on waiting lists, the monitoring of lists and the way in which these are kept up to date, the extent to which services are using central guidance, and whether any methods of list management had lead to inappropriate delays to treatment.

Following this review some recommendations were made. Firstly, patients should be routinely informed about the waiting times. Secondly, to reduce the DNA rate, patients should be contacted regularly to ensure that circumstances have not changed. Thirdly, all services should have early warning systems and plans to identify and manage potential waiting list problems. Finally, services

should give information to patients, GPs, and the public about waiting lists and waiting times.

The Scottish Executive (2003) produced a good practice guide to managing waiting times. Their guidance supported the recommendations of the Audit Scotland review (2002) and built on the commitments in the White Paper 'Partnership for Care'. The 'Managing Waiting Times' report (Scottish Executive, 2003. Page 6) claimed that waiting times were important to patients because: The patient's condition could deteriorate while waiting, and in some cases the effectiveness of the proposed treatment may be reduced. The experience of waiting could be distressing. The patient's family life and employment circumstances could be adversely affected by waiting. The report noted that 'a short period of waiting which is managed in the patient's best interests could support the scheduling of routine and emergency care and ensure the most urgent patients are seen first', but that 'excessive waiting times must be reduced'(Page 6). The report stated that services must:

- Manage demand by ensuring each referral represents the most appropriate decision for the care of the individual patient.
- Manage the queue by ensuring waiting lists are well managed and patients are called for treatment in appropriate order.
- Manage capacity by providing efficient and effective services that meet the level of demand from appropriate referrals.
- Provide leadership by ensuring that all parts of the local NHS work together to achieve waiting time improvements in the best interests of patients.

The waiting list for Clinical Psychology services in the east area of Glasgow had been identified as a problem. To prevent the wait from becoming excessive ways of managing the waiting list were investigated. Looking at the current literature two points seemed most relevant; firstly, that 'all services should have early warning systems and plans to identify and manage potential waiting list problems' (Audit Scotland, 2002. Page 46), and secondly that the service must 'manage capacity by providing efficient and effective services that meet the level of demand from appropriate referrals' (Scottish Executive, 2003. Page 7). It was decided that running evening clinics in addition to the routine daytime service would be a way of managing capacity in the Clinical Psychology service. Evening clinics are a short-term way to increase clinical activity, treat a backlog of patients on a waiting list, and improve waiting times.

Future evening clinics are being proposed and negotiations regarding funding are currently taking place in the east area of Glasgow. This audit provides an overall view of clinical activity at the evening clinics. The data displayed and discussed in this report should inform decisions about the future use and provision of evening clinics to be made at a management level.

### Aims

The aim of this audit was to provide a description of the evening clinics, focussing on the uptake of this additional service.

### Audit Questions

- How many appointments were available at the evening clinics?
- How many new people were seen at the evening clinics?
- How many of the appointments at the evening clinics were taken up?

- How many people attended the evening clinics?
- How many times did people attend the evening clinics?
- How many people were discharged at the end of the evening clinics?
- How many people carried on in the service once the clinics had finished?
- What was the immediate impact on the waiting list in the usual day-time service?

### Methodology

The majority of data for this audit were taken from a 'Waiting List Initiative Database' kept by the east area of Glasgow Clinical Psychology service. This database was designed specifically to record audit data and was kept in addition to routine data collection methods. Separate files were kept for each clinic. The database was examined closely. Any gaps in the data were followed up and completed from paper-based records. Information recorded on the database included:

- A weekly breakdown of activity for each clinician
- A record of annual leave and sick leave for each clinician
- How many patients attended, did not attend (DNA) and cancelled for each clinician
- Time used for supervision and administration
- How many patients attended, DNA and cancelled each week
- The outcome at the end of each clinic – how many patients were discharged and how many carried on into the usual day-time service

The sample consisted of two hundred and twenty-four patients in total, one hundred and seven from the first clinic and one hundred and seventeen from

the second clinic. Patients were taken from the top of the routine waiting list, i.e. those who were longest waiting, no exclusion criteria or screening methods were applied.

The evening clinics were analysed separately using an array of descriptive statistics, and then compared to see if any differences emerged. Following this the two sets of information were combined to give an overall picture of activity at the evening clinics. The Patient Information Management System (PIMS) was used to obtain data regarding rates of attendance, non-attendance and cancellation for a sample of the patients attending the usual day-time service. PIMS was also used to collate figures for waiting list numbers and waiting times. The PIMS system was used as a daily data collection tool, but was not specifically designed to collect audit data. Some clinicians did not complete PIMS records and often accurate figures were not available from this system.

## Results

The audit questions listed in the introduction are addressed in order.

- How many appointments were available at the evening clinics?

The first evening clinic was run by four clinicians for six months, providing one hundred and forty-six time slots. A one hour session is defined as one 'time slot'. Patients were seen in one hundred and eleven (76%) of these slots and the other thirty-five (24%) were used for supervision and administration.

The second evening clinic was run by three clinicians for the first month and then five clinicians for four months, providing one hundred and fifty-nine time slots, one hundred and thirty-one (82%) of which were used for patients and twenty-eight (18%) for supervision and administration. Together the clinics provided three hundred and five time slots, two hundred and forty-two (79%) of these were used to see patients.

- How many new people were seen at the evening clinics?
- How many of the appointments at the evening clinics were taken up?
- How many people attended the evening clinics?
- How many times did people attend the evening clinics?

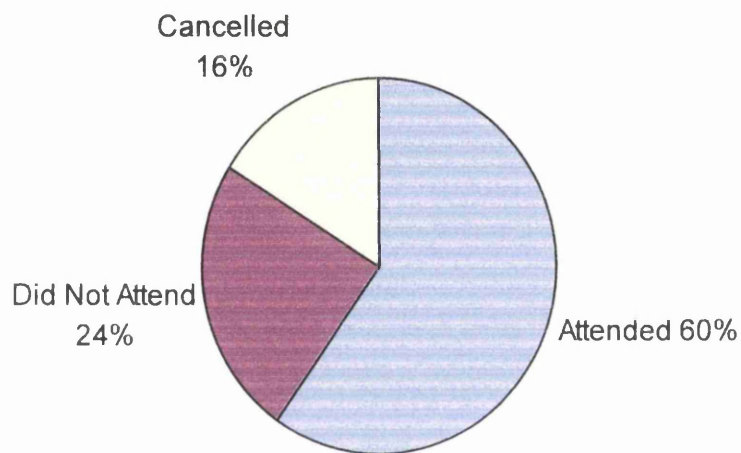
In total two hundred and twenty-four people were offered appointments at the evening clinics between October 2002 and January 2004, with one hundred and seven appointments at the first clinic and one hundred and seventeen at the second. This resulted in two hundred and twenty-four new patients being taken off the waiting list. Table one shows the use of these appointments for both clinics and an overall picture.

Table 1 – Breakdown of Appointment Outcomes.

	<b>Attended</b>	<b>Did Not Attend</b>	<b>Cancelled</b>
<b>Clinic 1</b>	62	34	11
<b>Clinic 2</b>	72	20	25
<b>Overall</b>	134	54	36

Table one shows that the majority of appointments were attended, with the levels of non-attendance and cancellation varying between the two clinics. The graph below gives an overall picture of how appointments were used by patients.

Graph 1 – Appointment use



Graph one shows that over half (60%) of the appointments given at the evening clinics were attended. Cancellations and non-attendance made up the remaining 40% of appointment use. The number of times that people attended appointments during the evening clinics varied. On average people attended two sessions each out of the appointments that were offered, this figure takes into account those patients who did not attend, who cancelled, and also those who attended one or more than one appointment.

The rates of attendance, non-attendance and cancellation were compared to the rates for the usual day-time service.

Table 2 – A Comparison of Appointment Outcomes for Evening and Daytime

Clinics.

	<b>Attended</b>	<b>Did Not Attend</b>	<b>Cancelled</b>
<b>Daytime Clinic</b>	160	54	36
<b>Evening Clinic</b>	134	58	32

Table two illustrates that attendance for the day-time service was slightly higher, one hundred and sixty (64%) compared to one hundred and thirty-four (60%) for the evening clinics. The rates of non-attendance were similar fifty-four (23%) for the day-time service and fifty-eight (24%) for the evening clinics. Rates of cancellation were also similar with thirty-six (13%) for the day-time service and thirty-two (16%) for the evening clinics. Figures for the day-time service were obtained by looking at attendance, non-attendance and cancellation rates for the last two hundred and fifty new contacts on the Patient Information Management System (PIMS) in March 2005. As previously mentioned using the PIMS system to obtain audit data did have limitations, therefore this comparison can be used to give a very general overview of the differences between the usual day-time service and the evening clinics.

- How many people were discharged at the end of the evening clinics?
- How many people carried on in the service once the clinics had finished?

Following these appointments patients took various routes through the service. Some patients did not attend any appointments or cancelled and did not require any further input, they were discharged. Other patients attended one or more appointments and were discharged from the service at various points.



Table 3 – Outcome at the end of Evening Clinics

	<b>Discharged</b>	<b>Day-time Appointment</b>
<b>Clinic 1</b>	34	63
<b>Clinic 2</b>	32	10
<b>Overall</b>	66	73

Table three shows that at the end of the first evening clinic thirty-four (32%) patients were discharged and sixty-three (59%) carried on into usual day-time appointments. When the second clinic ended thirty-two (27%) patients were discharged, and ten (9%) patients carried on into the usual day-time service. Overall sixty-six patients were discharged (29%) and seventy-three (33%) required further input. Other patients who had been offered appointments were discharged before the end of the clinics for various reasons.

- What was the immediate impact on the waiting list in the usual day-time service?

The five months before the start of the first evening clinic (May to September 2002) the average number of people on the east area waiting list was five hundred and fifty-eight. In the five months after the first clinic and before the second clinic (April to August 2003) the waiting list was five hundred and forty-one, a three percent reduction. In the five months after the second evening clinic ended (February to June 2004) the waiting list was four hundred and seventy-two, a fifteen percent reduction.

## Conclusions & Recommendations

The results across both clinics were compared on a number of dimensions.

Firstly, the number of appointments available was similar for both clinics, one hundred and eleven and one hundred and thirty-one, giving an overall total of two hundred and forty-two. Both clinics took a similar amount of new patients off the waiting list. The rates of attendance, non-attendance and cancellation were also similar for clinics one and two. The amount of sessions used for patients, supervision and administration were alike for both clinics. At the end of the evening clinics thirty-two percent of patients were discharged from the first clinic and twenty-seven percent from the second, again similar values.

The main difference between the two evening clinics emerged when looking at the figures for patients who carried on into the usual day-time service; fifty-nine percent from clinic one carried on into day-time appointments compared to only nine percent of patients from clinic two. There are many reasons why this difference may have occurred, some of which can be speculated upon. Two obvious differences that existed between the two clinics were that more sessions were available at the second clinic and more experienced clinicians ran the sessions. Many variables are present in every Clinical Psychology service such as case complexity, waiting list pressures, departmental guidelines regarding number of treatment sessions, experience of clinicians, etc. All of these factors could have played a part in this difference between the two clinics.

An overall view of the clinics revealed that they provided three hundred and five time slots, 79% of which were used to see patients. Two hundred and twenty-four new patients were taken off the waiting list. Sixty percent of the

appointments given at the evening clinics were attended. People attended an average of two sessions each out of the appointments that were offered. At the end of the clinics twenty-nine percent of patients were discharged and thirty-three percent were offered further input.

The overall view of attendance, non attendance and cancellation rates at the evening clinics was compared to rates for the usual day-time appointments. Attendance for the day-time service was slightly higher, sixty-four percent compared to sixty percent for the evening clinics. The rates of non-attendance and cancellation were similar. The evening clinics appeared to be taken up in a similar way to the daytime appointments. As previously mentioned there were differences between data sets for the routine daytime service and the evening clinics. The data collected for the evening clinics was collected on a separate database designed to record audit information. Data for the daytime service was collected on the PIMS system which was used for routine information recording. The PIMS system was not completed by all clinicians and often had technical faults which made the data inaccurate. Due to the differences in data sets for the evening clinics and the daytime service it was not considered to be meaningful to look at the statistical significance of any differences between the two services.

The immediate impact of the evening clinics upon the usual day-time waiting list was examined. There was a fifteen percent reduction in the waiting list following the second evening clinic, but only a three percent reduction after the first clinic. These figures are only approximate and must be treated with caution as numerous factors can impact upon a waiting list.

Factors such as referral rates, staffing levels, complexity of cases, etc. can all impact upon the waiting list. One difference between the two clinics which may have had an impact is the difference in numbers of patients who carried on into the usual day-time service. At the end of clinic one fifty-nine percent of patients carried on into day-time appointments compared to only nine percent of patients from clinic two. The large percentage of patients who were offered further input at the end of the first clinic could have resulted in less patients being taken off the waiting list as appointments would be taken up by patients from the evening clinic. At the end of the second clinic fewer patients were offered further input in the day-time service, possibly leaving more available appointments for people on the waiting list to be seen in the usual day-time service.

Another factor which could have had an impact on the waiting list was the fact that extra clinicians who did not routinely work in the daytime service worked at the evening clinics. The routine daytime service continued as normal, but was supplemented by additional appointments in the evening. The daytime service was under staffed at the time of the clinics due to unfilled vacancies. By providing extra sessions in the evening the service prevented the waiting list from becoming any longer, and reduced it by fifteen percent at the end of the second clinic. These staffing levels could explain the small reduction in the waiting list following the first clinic (3%); instead of a large reduction in the waiting list the service prevented an increase.

When considering the overall view of the evening clinic data certain suggestions for the future could be made. One suggestion is to shift the focus of the

evening clinics to a type of assessment or screening exercise. Given that in total twenty-nine percent of patients were discharged and thirty-three percent required further input at the end of the evening clinics, this leaves thirty-eight percent who were discharged for various reasons before the end of the clinics. An initial assessment clinic could help to identify those patients who require input and those who would be willing to attend sessions. This way of using the clinical time could allow a large number of patients to be assessed in preparation for offering day-time appointments.

The practical and ethical issues related to evening clinics must also be considered. Safety for members of staff working after usual hours is one such issue. A suitable building with extra secretarial staff was used to run the first two evening clinics. This type of arrangement would need to be made for any future clinics. Extra staff time was another practical issue. Staff came from other services to provide sessions in the evening clinics, in addition to clinical and secretarial staff from the routine daytime service. This meant extra funding to pay all staff at the appropriate rate for working out of hours. These factors must be considered alongside the patient data when looking at the future uses of the evening clinics.

Further data from the third evening clinic, which is being negotiated at present, could be added to the existing data set. It would be useful to look at any trends that emerged from the data, especially in terms of the number of patients who carried on into the day-time service given that there is a notable difference clinics one and two. Any other differences and similarities would also provide extra information to help guide the future direction of evening clinics. The aim

of this audit was to provide a description of the evening clinics, focussing on the uptake of this additional service. Further investigation into other factors which have an influence on the waiting list would also help to provide a more accurate picture of the true impact of running evening clinics as a waiting list initiative. Further work on comparing the routine daytime service and the evening clinics would also help to determine how viable the evening clinics were.

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## **Chapter 2: Systematic Literature Review**

The prevalence of anxiety and depression in men with prostate cancer:

A systematic review of the literature

Prepared in accordance with requirements for submission to Psycho-Oncology

(see Appendix 2.1)

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## **Abstract**

This systematic review aimed to address the following questions: 'What is the prevalence of anxiety and depression in men with prostate cancer?' and 'Is there a relationship between anxiety, depression and sexual dysfunction in men with prostate cancer?' The purpose of the review was to investigate the quality of studies looking at levels of anxiety, depression and sexual dysfunction in a systematic way. An electronic search of suitable health databases was completed using five key terms to reflect the main components of the systematic review question. Twelve studies were then identified using inclusion and exclusion criteria and included in this review. The methodological quality of each of the twelve studies was examined using assessment criteria adapted from the Scottish Intercollegiate Guidelines Network (SIGN) 50 'A Guideline Developers' Handbook' [1]. Reported prevalence levels for 'clinically significant' anxiety ranged from 32.6% to 6.7%. Prevalence rates for 'clinically significant' depression ranged from 2% to 27%. Reported prevalence of sexual dysfunction ranged from 40 to 80%. Limitations of the current literature are discussed and suggestions for future research are proposed.

**Keywords** – Prostate, cancer, anxiety, depression, sexual dysfunction.

## Introduction

### *Prostate Cancer*

Prostate cancer affects nearly thirty-two thousand men per year in the United Kingdom and causes ten thousand deaths per year [2]. Being diagnosed with and treated for prostate cancer involves a complex set of biological and psychological factors. Men who are treated for prostate cancer and survive often face many treatment-specific side effects afterwards [3]. One side effect that is commonly reported is sexual dysfunction [4, 5]. All prostate cancer treatments involve varying degrees of medical intervention. These interventions range from surgery to regular check ups and PSA tests (active monitoring). Surgery, radiotherapy, brachytherapy and hormone therapy are all effective in the treatment of prostate cancer but have associated side effects. Side effects include: urinary incontinence, sexual dysfunction, bowel problems, hot flushes, breast swelling and tenderness, weight gain and osteoporosis. Urinary incontinence and sexual dysfunction are caused by all four of the treatments described above. Sexual dysfunction includes: loss of libido, infertility, erectile dysfunction, inability to orgasm, etc. The need for a better understanding of patients' psychological needs at various stages of prostate cancer diagnosis and treatment has been highlighted [4].

### *Psychological Distress*

Many studies have reported that cancer and psychological problems, such as anxiety and depression, often co-occur [6]. General theoretical psychological models of why people may experience anxiety and depression have been used in relation to cancer patients [7, 8]. Models of Post-traumatic Stress Disorder

have also been used to explain some of the psychological symptoms that people experience following a diagnosis of cancer and subsequent treatment [9]. Manzanera et al. (2003) assessed a sample of 54 patients with various types of cancer using the Hospital Anxiety and Depression Scale [11]. They found that 32% reported depressive disorders and 30% anxiety disorders [10]. Kollner, Lautenschlager and Pajonk (2004) reported in their review paper that the frequency of co-occurrence is approximately 50% and that depression, anxiety and possibly post-traumatic stress disorder are the problems most relevant in prostate cancer.

### *Sexual Dysfunction*

Matthew et al. (2005) reviewed the literature related to sexual dysfunction following radical prostatectomy from 1966 to 2004. They found that several studies reported that 44% to 75% of men experienced sexual dysfunction, of whom more than 60% experienced distress because of their sexual dysfunction problems. Weber and Sherwill-Navarro (2005) reviewed 30 years of research on the 'psychosocial consequences' of prostate cancer. They stated that 'survivorship' in prostate cancer patients is commonly complicated by long-term disease-specific side effects, such as sexual and urinary dysfunction. Studies have shown that the psychological impact of prostate cancer continues long after the diagnosis and treatment phases have been completed. Baker, Denniston, Smith and West (2005) used the Cancer Problems in Living Scale (CPILS) to assess 752 patients, 97 of whom had prostate cancer. They found that a year on from diagnosis: 68% of patients were concerned about their illness returning, 58% had fears about the future, and 41% reported sexual dysfunction as a major concern.

A small, but increasing number of studies have begun to address the psychological impact of prostate cancer. In earlier studies the physical and psychological effects of being diagnosed with and treated for prostate cancer were mainly assessed using health-related quality of life measures [13]. Many papers have noted that studies of health-related quality of life focussed on physical well-being and paid relatively little attention to psychological functioning [14, 15, 16]. Bennett and Badger (2005) stated that the clinical significance of psychological distress experienced by men with prostate cancer had yet to be adequately addressed in the research literature. At the time of their project, Hervouet et al. (2005) identified four studies which evaluated the prevalence of depression and anxiety in prostate cancer patients using validated instruments; all of them used the Hospital Anxiety and Depression Scale. They noted prevalence rates of depression ranging from 3% to 15% and anxiety rates from 11% to 33%.

Crawford et al. (2001) administered the Hospital Anxiety and Depression Scale to a large non-clinical sample of adults in the United Kingdom. They found that on the HADS anxiety sub-scale the mean score was 6.14 and on the HADS depression sub-scale the mean score was 3.68. Crawford et al. [17] reported that on the HADS anxiety sub-scale 20.6% of the population scored between 8-10 (mild), 10% scored in the moderate range (11-15), and 2.6% scored 16 or above (severe). On the HADS depression sub-scale 7.8% of the population were in the mild range (8-10), 2.9% scored 11-15 (moderate), and 0.7% scored in the severe range (16 or above). These figures provide a useful point of comparison for prevalence rates in clinical populations.

The primary aim is to systematically review the current literature addressing the prevalence of anxiety and depression in prostate cancer patients. A secondary aim is to examine the prevalence of sexual dysfunction, and if there is any relationship between sexual dysfunction and anxiety and/or depression.

## **Method**

### *Objective*

This systematic review aimed to address the following questions:

- What is the prevalence of anxiety and depression in men with prostate cancer?
- Is there a relationship between anxiety, depression and sexual dysfunction in men with prostate cancer?

### *Search Strategy*

The following electronic databases were searched during this review:

Medline (1950 – 2007)

PsychInfo (1806 – 2007)

CINAHL (1982 – 2007)

EMBASE (1980 – 2007)

All EMB Reviews, including CDSR, ACP Journal Club, DARE, CCTR

### *Search Terms*

The electronic search used five key terms to reflect the main components of the systematic review question.

- 1) Prostate
- 2) Cancer
- 3) Anxiety
- 4) Depression
- 5) Sexual Dysfunction
- 6) 1,2,3 & 4 combined using AND
- 7) 1,2,3, 4 & 5 combined using AND

All duplicates were removed. The reference lists for articles were also reviewed. Hand searches of Psycho-oncology and the Journal of Psychosocial Oncology were also completed (1997-2007).

### *Inclusion Criteria*

- Participants aged 18 years or over
- Participants with a primary diagnosis of Prostate Cancer
- Studies using an outcome measure for anxiety and/or depression
- Peer reviewed journal articles
- English Language journal articles
- Studies addressing the incidence and prevalence of anxiety or depression in prostate cancer patients
- Studies addressing the incidence and prevalence of sexual dysfunction in prostate cancer patients

## **Results**

### *Search Results*

Initial searches using electronic databases generated 436 possible papers. The titles and abstracts of these papers were reviewed. Four hundred and six papers were considered not to be relevant to the review question on the basis of their abstracts and were excluded. Thirty papers were retained as being relevant to the review question. Following a hand search of key journals and reference lists of papers from the electronic search a further 2 papers were identified as potentially suitable (see Appendix 2.2).

### *Excluded Studies*

The full articles for the 32 potentially suitable studies were reviewed. Following this, a further 20 studies did not meet the inclusion criteria for this review. Nine of the latter papers were non English language and so were excluded. Five papers were letters, editorials or reviews [20, 21, 22, 23, 4]. Three studies did not use an outcome measure to assess anxiety and/or depression [24, 25, 26]. Two papers included participants whose primary diagnosis was not solely prostate cancer [27, 28] and were therefore, excluded. One other paper was not a peer reviewed journal article [29] and was also excluded.

### *Included Studies*

Twelve studies were included in the review:

- Bisson et al., 2002 [16]
- Balderson & Towell, 2003 [30]
- Roth et al., 1998 [15]
- Lintz et al., 2003 [31]
- Hervouet et al., 2005 [19]
- Rosenfeld et al., 2004 [14]
- Cliff & MacDonagh, 2000 [32]
- Korfage et al., 2006 [33]
- Ene et al., 2006 [34]
- Steineck et al., 2002 [35]
- Sharpley & Christie, 2007 [36]
- Soloway et al., 2005 [37]



### *Data Extraction*

Data were extracted from each of the included studies. The data were relevant to the aim of the review and related to the design and quality of the study. A summary of the data extracted from each study is shown in Table 1.

### *Quality Assessment*

The methodological quality of each of the 12 studies was examined using assessment criteria adapted from the Scottish Intercollegiate Guidelines Network (SIGN) 50 'A Guideline Developers' Handbook' (SIGN, 2004). The criteria assessed 24 factors including; research aims, hypotheses, population, design, outcome measures, results and analysis (see Appendix 2.3). Score totals ranged from 0 to 48, where individual ratings were a possible score of 0 (Not addressed, not reported or not applicable), 1 (poorly addressed), or 2 (adequately addressed or well covered) on each item. The reviewer and the independent examiner were not blind to study details, such as, author, journal or organisations conducting the research. Scores for each study are shown in Table 1.

### *Reliability of Quality Assessment*

An independent examiner also rated all studies included in this review using the same quality assessment criteria. Eighty-seven percent agreement was found between raters. Raters met to discuss any disagreements in scoring.

### **Review of Studies**

Studies will be discussed in ascending order of total scores. All twelve of the papers included in this review investigated levels of anxiety and depression in

prostate cancer patients as a part of the study. Six of the studies included in the review also addressed levels of sexual dysfunction [19, 35, 31, 32, 30, 37].

Hervouet et al. (2005) investigated the prevalence of anxiety and depression in 861 prostate cancer patients who received different treatments. They conducted a cross-sectional comparison of patients treated with radiotherapy, brachytherapy or surgery (radical prostatectomy) within the last seven years. Hervouet et al. (2005) used the Hospital Anxiety and Depression Scale [11] to assess levels of anxiety and depression. The HADS was considered to be a reliable, valid and sensitive measure suitable for use with this population. A cut off score of 7 or higher on the HADS anxiety or depression subscales was used to indicate the presence or absence of clinically significant levels of depression or anxiety. A total HADS score of 15 or more was used to identify clinically significant levels of global psychological distress. These cut offs were taken from previous studies with cancer populations [15, 38]. Hervouet et al. (2005) reported that 23.7% of their total sample had clinically significant levels of anxiety, 17% were above the cut off for depression, and 14.6% above the cut off for global psychological distress.

The treatment groups in this study were not well matched and significant differences existed between them on a number of demographic and medical factors. Patients were not randomised into treatment groups and a control group was not recruited for this study. Hervouet et al. (2005) reported that radiotherapy patients generally had a poorer prognosis and were more likely to have co morbid illnesses than the other two treatment groups. However, radiotherapy patients were reported to have significantly higher levels of

depression and global psychological distress than brachytherapy or surgery patients, after controlling for these covariates. Radiotherapy patients were also found to have significantly higher levels of anxiety compared to brachytherapy patients. Hervouet et al. (2005) concluded that radiotherapy patients were more likely to be at risk of psychological distress but that their study did not demonstrate a clear link between treatment group and level of distress.

Hervouet et al. (2005) also investigated sexual difficulties using the Prostate Cancer-Specific Module (PCSM), which is a supplement to the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire (EORTCQLQ-C30). The PCSM sexuality scale consists of 4 items rated on a Likert scale from 1 (not at all) to 4 (a lot). Scores are then converted on a scale of 0-100. They used 50% as a cut off for clinically significant difficulties for the purposes of this study. The PCSM was translated by the research team but had not been empirically validated for use prior to use in this study. Hervouet et al. (2005) reported that 70.5% of the total patient sample scored above 50% on the sexual difficulties scale of the PCSM. Hervouet et al. (2005) reported that the finding that radical prostatectomy (RP) was associated with a lower likelihood of clinical levels of depression compared to not having surgery was surprising, considering higher prevalence of sexual dysfunction in the RP group. They suggest that this implies that levels of sexual dysfunction are not necessarily associated with mood impairments. Hervouet et al. (2005) did not consider the age of patients when analysing their results for sexual difficulties.

Korfage et al. (2006) aimed to look at anxiety and depression in 299 prostate cancer patients, from pre-treatment to 5 year follow-up. Patients were non-randomly allocated to radical prostatectomy or radiotherapy treatment groups. A control group was not recruited. Patients completed three validated self-report questionnaires; the State Trait Anxiety Inventory (STAI), the Centre for Epidemiological Studies Depression Scale (CES-D), and the Mental Health scale from the RAND 36-item Short-Form Health Survey (SF-36). The questionnaires were completed pre-treatment, at 6 months, 12 months and 5 years. Following pre-treatment assessment scores on the STAI were used to divide patients into four groups: radical prostatectomy and high anxiety, radical prostatectomy and low anxiety, radiotherapy and high anxiety, radiotherapy and low anxiety. STAI scores below 44 were defined as 'low anxiety'; this cut off was taken from previous studies [39]. Statistical analysis revealed that there were significant differences between the groups in relation to age, co morbid conditions and PSA levels. Korfage et al. (2006) reported that pre-treatment, 28% of all patients reported clinically significant levels of anxiety, 25% of the surgery group and 30% of the radiotherapy group. Scores for men treated by surgery (radical prostatectomy) were better than those treated by radiotherapy for all three measures and at all four assessment points. Scores were also analysed in terms of 'high anxiety' and 'low anxiety' groups. No significant differences between 'high anxiety' and 'low anxiety' groups were found for scores on the CES-D. A score of 16 or above on the CES-D was considered to be clinically significant. At all assessment points a lower percentage of men treated by radical prostatectomy (9-18%) reported clinically significant levels of depression compared to the general population (20%). Pre-treatment (27%) and at 5 years follow-up (22%) the percentage of men with clinically significant

levels of depression in the radiotherapy group was higher than the general population (20%). Complete data on prevalence of depression in the sample have not been presented in this paper. Korfage et al. (2006) did not assess levels of sexual dysfunction in this study.

Steineck et al. (2002) recruited 326 men, who were randomly allocated to radical prostatectomy (RP) or watchful-waiting (WW) treatment groups. No data were provided on the matching of these groups. The aim of the study was to evaluate symptoms and quality of life after radical prostatectomy or watchful-waiting. A questionnaire designed for the study was used with the CES-D and the trait measure from STAI added to it. No reliability or validity data for this measure was provided. Using the CES-D Steineck et al (2002) reported that 7% of RP patients and 11% of WW patients scored above the 90<sup>th</sup> percentile. On the STAI 9% of RP and 10% of WW patients scored above 90<sup>th</sup> percentile. Further data regarding scores on the CES-D and STAI trait measure were not reported. Steineck et al. (2002) used a range of questions covering; desire, erection, intercourse, orgasm, ejaculation and distress from compromised sexuality to assess sexual dysfunction. Steineck et al. (2003) reported that 45% of patients in the watchful waiting group reported erectile dysfunction and 40% were distressed by the decline in their sexual function, compared to 80% reporting dysfunction and 56% reporting distress in the radical prostatectomy group. Full data were not provided to allow any conclusion to be made regarding any relationship between levels of sexual dysfunction and anxiety levels on the STAI or levels of depression on the CES-D.

Bisson et al. (2002) recruited 88 newly diagnosed prostate cancer patients with the aim of determining the prevalence and predictors of psychological distress in this group. Patients completed five questionnaires, including the HADS and the 30-Item General Health Questionnaire (GHQ-30), before their first assessment and then again two weeks later. Bisson et al. used a threshold of 10/11 on the HADS subscales and the GHQ-30 to detect clinically significant psychological distress, but did not state why they were using this cut off or quote other studies using this value. Bisson et al. (2002) stated that both measures had been validated for use with cancer populations and provided references. In the results section scores on the HADS anxiety and depression subscales were reported for thresholds of 7/8 and 10/11. At the first assessment 22% of patients scored 7 or above on the anxiety subscale, and 10% scored 10 or above. On the depression subscale 5% of patients scored 7 or above, and no scores were 10 or above at the first assessment. On the GHQ-30 scores were reported for thresholds of 4/5 and 10/11. Twenty-five percent of the participants scored 4 or above and 9% scored 10 or above on the GHQ-30 at the first assessment.

Only 61 men went on to complete the second assessment two weeks later. Mean scores on the HADS were compared for these 61 men. At the first assessment a mean score of 5.11 was obtained on the anxiety subscale, decreasing to 4.38 at the second assessment. On the depression subscale a mean score of 1.79 at first assessment increased to 2.46 at the second assessment. Bisson et al. (2002) reported that the HADS anxiety subscale score was significantly lower at the second assessment, and the depression subscale score was significantly higher. However, mean scores for anxiety and

depression were below clinically significant levels at the first and second assessments. The GHQ-30 was not repeated at the second assessment. Bisson et al. (2002) did not address levels of sexual dysfunction in their study.

Lintz et al. (2003) aimed to investigate the support and psychological care needs of men with prostate cancer. Two hundred and ten prostate cancer patients from a randomly pre-selected sample took part and completed four questionnaires including the HADS. No control group was recruited for this study. The mean anxiety score on the HADS subscale was 4.2. Two percent of patients scored 11 or more, 12.3% scored 8 to 10, and 85.7% scored less than 8. The mean depression score on the HADS subscale was 3.4. One point four percent of patients scored 11 or more, 7.2% scored 8-10, 91.4% scored less than 8. Lintz et al. (2003) reported their results in terms of these HADS cut offs but did not explain how they were interpreted in the study or provide any references for cut off scores. They also reported that 12% of their sample had a 'premorbid psychiatric history', but did not control for this when analysing and interpreting their data.

Lintz et al. (2003) also investigated sexual difficulties using the Prostate Cancer-Specific Module (PCSM). They also included further questions on sexuality using the Support Care Needs Survey (SCNS). On the SCNS they reported that 35% of men reported support needs on 'feeling you've lost part of your manhood', 41% for 'changes in sexual feelings', and 36% in 'changes in sexual relationships'. On the PCSM 78% had had some difficulty 'getting or maintaining an erection', 68% had experienced 'ejaculation problems', 57% had

'felt uncomfortable about being sexually intimate'. However, despite these problems 89% had 'enjoyed sex' within the past 4 weeks.

Lintz et al. (2003) also divided their sample into men who were over 65 years old and men who were 65 or less for their analysis; however, they did not state how many men from their sample fell into each age range. They reported that on the SCNS men who were 65 or less had higher levels of sexual interest and activity. On the PCSM men who were 65 or less were more likely to feel uncomfortable being sexually intimate. Eighty-four percent of men who were 65 or less reported having some interest in sex, compared to 45% over 65.

Seventy percent of men who were 65 or less reported being sexually active compared to 11% over 65. It was stated that results on PCSM showed that men who were 65 or less were significantly more interested in sex and more sexually active than men who were over 65 years of age. Lintz et al. (2003) reported their PCSM results in a way which differed from Hervouet et al. (2005) making comparison problematic and full data were not provided in either study. Lintz et al. (2003) did not discuss the presence or absence of any relationship between levels of anxiety or depression and sexual dysfunction. They also did not control for age when analysing and interpreting HADS anxiety and depression scores, despite finding differences between men of over and under 65 on the PCSM and SCNS.

Ene et al. (2006) aimed to investigate patients' experience of pain, psychological distress and their health-related quality of life at baseline and 3 months after radical prostatectomy. A sample of 140 patients completed three questionnaires including the HADS. Ene et al. (2006) reported that the HADS



was a reliable and valid measure. On both the depression and anxiety subscales they used scores of 7 or less to indicate no distress, 8-10 to indicate possible anxiety or depression, and 11 plus to indicate probable anxiety or depression. They reported that 77% of patients had no anxiety symptoms at baseline compared to 92% post-surgery. Eighty-nine percent of patients did not have any symptoms of depression at baseline compared to 91% post-surgery. The mean anxiety score on the HADS subscale was 5.0 and the mean depression score on the HADS subscale was 3.0. At baseline 7% of patients scored 11 or more, 16% scored 8 to 10, and 77% scored less than 8 on the anxiety subscale. Two percent of patients scored 11 or more, 8% scored 8-10, 89% scored less than 8 on the depression subscale. Scores at 3 months mean anxiety score on the HADS subscale was 3.0 and the mean depression score on the HADS subscale was 2.6. At 3 months 5% of patients scored 11 or more, 3% scored 8 to 10, and 92% scored less than 8 on the anxiety subscale. Two percent of patients scored 11 or more, 7% scored 8-10, 91% scored less than 8 on the depression subscale. Ene et al. (2006) did not investigate levels of sexual dysfunction in this study.

Cliff and MacDonagh (2000) recruited 135 prostate cancer patients and their partners in order to assess psychosocial morbidity in prostate cancer patients, and compare their levels of distress to their partners. They used the HADS and a questionnaire developed by their own research group. Cliff and MacDonagh (2000) aimed to develop a new questionnaire for measuring psychosocial morbidity in men with prostate cancer and their partners. The reliability and validity of this questionnaire has yet to be established. The questionnaire included items on sexuality, general cancer distress, social and treatment

worries, pain and urinary symptoms. Cliff and MacDonagh (2000) reported that the HADS was a reliable and valid measure. On the depression subscale they used scores of 7 or less to indicate no distress and on the anxiety subscale scores of 8 or less. Scores of 8-11 indicated borderline anxiety or depression and scores of 11 plus indicated definite anxiety or depression. They reported that 6.7% of patients scored 11 or above on the anxiety subscale and 3.7% scored in this range on the depression subscale, indicating definite anxiety or depression. Eleven point one percent scored 8-11 on the anxiety subscale and 4.4% on the depression subscale. Eighty-two point two percent of patients did not have any symptoms of anxiety, and 91.9% of patients did not report any depressive symptoms. They reported mean scores for worries about sex of 2.1 out of 4. Results were then analysed in terms of HADS morbidity, on the depression subscale scores of more than 7 were taken to indicate morbidity and on the anxiety subscale scores of more than 8. Cliff and MacDonagh (2000) reported that 45% of patients below the HADS cut off on either subscale had worries about sexuality, and 65% above the cut off. The questionnaire did not include items looking at sexual dysfunction specifically.

Balderson and Towell (2003) aimed to investigate the prevalence and predictors of distress in men with prostate cancer. Ninety-four men with prostate cancer completed three questionnaires including the HADS. They used a total HADS score of 15 or above to indicate clinically significant psychological distress. Thirty-eight percent of men scored 15 or above on the HADS. The mean score on the anxiety subscale was 7.17, 5.09 on the depression subscale, and an average of 12.30 for the total HADS score. Participants were recruited from

support groups, which Balderson and Towell argued, might account for higher reported levels of distress.

Balderson and Towell (2003) also included a measure of sexuality in their study in the Functional Assessment of Cancer Therapy-Prostate Instrument (FACT-P). This is a 12-item scale, with acceptable reliability and validity, including questions on sexuality, bowel and bladder function, and pain. Balderson and Towell (2003) did not report sexuality scores separately, but as part of a general score. They reported that the mean FACT-P score was 33.09. No cut offs or norms were provided for the FACT-P. Balderson and Towell (2003) found that prostate-specific concerns measured using the FACT-P were significantly related to psychological distress assessed using the HADS.

Rosenfeld et al. (2004) recruited 341 men with prostate cancer in order to investigate differences in physical and psychological well-being based on stage of cancer. Patients completed the HADS and two further questionnaires addressing quality of life and urinary function. Medical data were then used to divide the men into three groups depending on stage of cancer; localised, locally advanced or metastatic. HADS scores were analysed in these three groups. Mean scores on the HADS anxiety subscale were 10.62 for the localised group, 10.16 for locally advanced patients, and 11.01 for the metastatic group. Mean scores on the HADS depression subscale were 12.02 for the localised group, 12.27 for locally advanced patients, and 12.65 for the metastatic group. Mean total scores on the HADS were 22.64 for the localised group, 22.43 for locally advanced patients, and 23.65 for the metastatic group. Rosenfeld et al. (2004) reported that there were no significant differences

between the groups in terms of HADS scores, and concluded that prostate cancer stage was unrelated to HADS total or subscale scores. Numbers of patients above any clinical cut off scores were not provided. Rosenfeld et al. (2004) did not investigate levels of sexual dysfunction in this study.

Sharpley and Christie (2007) recruited 183 prostate cancer patients and used the Self-Rating Anxiety Scale (SAS) and the Self-Rating Depression Scale (SDS) to investigate current and previous levels of anxiety and depression. They reported adequate reliability and validity of these measures, but did not refer to any studies that had used these measures or any reference to their suitability for use with cancer populations. Participants completed the SAS and SDS twice at one time point, once for how they felt currently and once for how they felt at the time of diagnosis. A raw score of greater than 36 on the SAS was taken as the cut off for having clinically significant anxiety. A raw score of above 40 on the SDS was given as the cut off for having clinically significant depression. When asked to rate themselves at diagnosis 20.2% of patients reported clinically significant anxiety symptoms, and 23.9% clinically significant depressive symptoms. When asked to rate themselves in the last week 12.6% of patients reported clinically significant anxiety symptoms, with the same percentage reporting clinically significant depressive symptoms. Sharpley and Christie (2007) did not investigate sexual dysfunction in this study.

Soloway et al. (2005) aimed to examine levels of sexual and psychological functioning of men with prostate cancer and their partners. They recruited 103 men who had recently been diagnosed with prostate cancer and their partners. Participants completed 7 questionnaires, including the Beck Depression

Inventory (BDI) and the Profile of Mood Sates (POMS). Patients had a mean score on the BDI of 5.63 and their partners had a mean score 8.13. Soloway et al. (2005) reported that 26.2% of patients were in the mild to moderate range on the BDI and 2% in the moderate to severe; none of the patients had scores in the severe range. They did not state the cut offs used to categorise these ranges. On the POMS patients had a mean score of 9.41 on the tension-anxiety subscale, and partners scored 11.69 on average. It was reported that these scores were within the normal range but no further information was provided.

The study by Soloway et al. (2005) was the only one, included in this review, to use specific measures of sexual functioning. Partners completed the Brief Index of Sexual Function for Women (BISF-W) and participants completed the Brief Sexual Function Questionnaire for Men (BSFQ) and selected questions from the Sexual Adjustment Questionnaire (SAQ). Patients had a mean SAQ total score of 51.70 and a mean BSFQ total score of 40.55. Partners had a mean SAQ total score of 51.75 and a mean BISF-W total score of 48.61. No cut off scores were given for either of these questionnaires. Soloway et al. (2005) compared mean scores for patients and partners on all of the dimensions of the BSFQ and the BISF-W with means for control populations. They concluded that prostate cancer patients reported similar levels of sexual activity and performance, but lower levels of satisfaction and interest. Partners reported higher levels of sexual initiation and receptivity, but also higher levels of problems affecting sexual function. Partners reported similar levels of frequency of sexual activity, but lower scores than controls for sexual thoughts and desires, arousal, pleasure and relationship satisfaction. No information

regarding the controls used for comparison was provided. Soloway et al. (2005) did not discuss the presence or absence of any relationship between levels of anxiety or depression and sexual dysfunction.

Roth et al. (1998) aimed to screen for psychological distress in men with prostate cancer. They recruited 93 patients and administered the HADS and 'the Distress Thermometer', which they described as a visual analogue scale rating emotional distress. During analysis Roth et al. (1998) used a total HADS score of 15 or above to indicate clinically significant psychological distress. On the HADS anxiety and depression subscales a score of 7 or above was used as cut off for symptoms of anxiety or depression. They reported that 13% of patients scored at or above the cut off for the total HADS score, 32.6% scored at or above the cut off on the anxiety subscale, and 15.2% scored at or above the cut off on the depression subscale.

## **Discussion & Conclusions**

### *Prevalence of Anxiety and Depression*

The primary aim of this review was to systematically evaluate the current literature addressing the prevalence of anxiety and depression in prostate cancer patients.

Many of the studies included in this review used the Hospital Anxiety and Depression Scale [11] to assess levels of anxiety and depression in prostate cancer patients. Reported prevalence levels for 'clinically significant' anxiety using the HADS subscale ranged from 32.6% [15] to 6.7% [32]. Anxiety prevalence rates using other measures were: 28% [33] and 9/10% [35] on the

STAI, 12.2-20.6% on the SAS [36]. Prevalence levels for 'clinically significant' depression on the HADS subscale ranged from 2% [31] to 17% [19]. Depression prevalence rates using other measures were: 7-27% on the CES-D [35, 33], 12.6-23.9% on the SDS [36], and 2% on the BDI [37].

Whilst investigating the reported prevalence of anxiety and depression in men with prostate cancer a number of methodological limitations in the existing literature became apparent. Firstly, many of the studies used the HADS, which they reported was a valid and reliable measure suitable for use with cancer patients. However, there was little agreement regarding scores considered to be 'clinically significant'. Some studies considered scores of 7 or above on the HADS anxiety and depression subscales to indicate 'clinically significant' anxiety or depression [19, 15]. Other studies used scores of 8-11 to indicate possible or borderline anxiety or depression, and scores of 11 or more to indicate definite anxiety or depression [34, 31, 32, 17]. Data were often reported in terms of these cut-off scores rather than individual scores, making comparisons between studies very difficult.

Further methodological problems were noted whilst assessing the methodological quality of the studies included in this review. None of the studies included power calculations to justify their sample sizes. Only one out of twelve studies [35] included any sort of control group (see Table 1). Many of the studies did not take into account confounding variables, such as age, which has previously been shown to be highly correlated with psychological distress in prostate cancer patients [21]. Due to the range of measures used, the incomplete data reported, and the cut-offs considered to demonstrate 'clinically

significant' anxiety or depression it was difficult to establish the prevalence of anxiety and depression in men with prostate cancer.

Some studies included in the review did attempt to overcome methodological difficulties. Three of the studies of better methodological quality, assessed using the methodological checklist (see Appendix 2.3 & Table 1), reported their results more fully [16, 19, 31]. Hervouet et al. (2005) reported their HADS data more fully in terms of total distress scores, and anxiety and depression subscale scores. Bisson et al. (2002) reported scores on the HADS anxiety and depression subscales for thresholds of 7/8 and 10/11. Lintz et al. (2003) reported HADS scores in terms of three different cut-offs, 11 or more, 8 to 10, or less than 8. Using the findings from these higher quality studies anxiety prevalence rates ranged from 23.7% [19] to 12.3% [31], prevalence rates for depression ranged from 17% [19] to 5% [16]. These prevalence rates did not appear to be much greater than rates reported by Crawford et al. (2001) for a non-clinical population. They found prevalence rates on the HADS anxiety sub-scale ranging from 2.6 to 20.6%, depending on the cut-off used to identify clinically significant levels [17]. They reported prevalence rates on the HADS depression sub-scale ranging from 0.7 to 7.8%, again depending on the cut-offs scores used.

### *Sexual Dysfunction*

A secondary aim of this review was to examine the prevalence of sexual dysfunction and any relationship between this and anxiety and/or depression. Six out of twelve studies included in the review addressed sexual dysfunction.



Hervouet et al. (2005) and Lintz et al. (2003) both used the PCSM to investigate sexual difficulties. Hervouet et al. (2005) used 50% as a cut off for clinically significant difficulties and reported that 70.5% of patients scored above this cut-off on the sexual difficulties scale. Lintz et al. (2003) reported that 57-78% of men reported having some difficulties with sexual function; 45-84% reported having some interest in sex, and 11-75% reported being sexually active. They also reported their results in terms of men aged 65 years and under or over 65. Lintz et al. (2003) reported their PCSM results in a way which differed from Hervouet et al. (2005) making comparison problematic and full data were not provided in either study.

Soloway et al. (2005) used the Brief Sexual Function Questionnaire for Men (BSFQ) and selected questions from the Sexual Adjustment Questionnaire (SAQ). They reported a mean SAQ total score of 51.70 and mean BSFQ total score of 40.55. No cut off scores were given for either of these questionnaires. The other two studies [35, 32] used their own questionnaires, neither of which had established reliability or validity. Steineck et al. (20003) reported that 45 to 80% of patients reported erectile dysfunction and 40 to 56% were distressed by the decline in their sexual function. Cliff and MacDonagh (2000) reported mean scores for worries about sex of 2.1 out of 4.

Cliff and MacDonagh's (2000) study was the only one in the review to make any comment regarding a relationship between sexual dysfunction and anxiety and/or depression. They reported that 45% of patients below the HADS cut off, and 65% above the cut off, had worries about sexuality.

Further methodological limitations were noted when considering sexual dysfunction. Studies in this review measured sexual dysfunction as part of a health-related quality of life measure rather than using a specific sexual function questionnaire, with the exception of one study [37]. Studies using the same measures did not provide full data and reported their results in a way which made comparison problematic [31, 19]. Due to the lack of valid and reliable measures of sexual dysfunction used and the way the data were reported it is difficult to reach any conclusions regarding the prevalence of sexual dysfunction, or if there is any relationship between sexual dysfunction and anxiety and/or depression.

In summary, studies reported clinically significant levels of anxiety in up to 32.6% [15] of the sample and clinically significant levels of depression in up to 37% [33] of participants. Although the current literature has a number of limitations, which have been discussed, it does provide useful information regarding the prevalence of anxiety and depression in men with prostate cancer. In terms of sexual dysfunction, data were presented in a range of ways, which made comparison problematic; however, studies reported that up to 78% [30] of the sample had difficulties in this area. Links between anxiety, depression and sexual dysfunction were not fully addressed by any of the studies; however, one study [32] reported that 65% of participants above the cut off for clinically significant anxiety and/or depression on the HADS had worries about sexuality.

### *Future Research*

Future research should aim to overcome the methodological limitations. Firstly, it would be important for future research to use valid and reliable measures of psychological and sexual functioning, rather than including them in a health related quality of life measure. Secondly, researchers should report results fully and in a way that makes comparison with other studies possible. Researchers should also aim to recruit a control group and calculate the sample size required for their study. This review has established that sexual dysfunction, anxiety, depression, and any relationship between these factors in men with prostate cancer require further investigation.

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**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Balderson & Towell, 2003 The prevalence and predictors of psychological distress in men with prostate cancer who are seeking support	24	Cross-sectional No groups	N=94 Mean age=66.87 Range=51-86 Power not stated	HADS, FACT-P, additional questions related to satisfaction with medical care	Mean HADS anxiety=7.17 Mean HADS depression=5.09 Mean HADS total=12.30 38% had a total HADS score of 15+	No further data on HADS subscale scores provided
Bisson, Chubb, Bennett, Mason, Jones & Kynaston, 2002 The prevalence and predictors of psychological distress in patients with early localised prostate cancer	28	Prospective No groups	N=88 Mean age=64.5 Range=48-78 Power not stated	HADS, Impact of Event Scale-Revised(IESR), 30 Item General Health Questionnaire (GHQ30), EORTCQLQ-C30, VAS 0-100	Assessment 1: 22% 7+ on HADS anxiety subscale 5% 7+ on HADS depression subscale Mean HADS anxiety=5.11 Mean HADS depression=1.79 25% 4+ on GHQ-30 9% 10+ on GHQ-30 Assessment 2: Mean HADS anxiety=4.38 Mean HADS depression=2.46	GHQ-30 not repeated at assessment 2

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Cliff & MacDonagh, 2000	26	Cross-sectional	N=135	HADS, other questionnaire developed by research team	Patients Mean HADS anxiety=4.3 Mean HADS depression=3.3	
Psychosocial morbidity in prostate cancer: II. A comparison of patients and partners		2 groups – patient and partner	Patients N=135 Patients mean age=73.9		HADS anxiety subscale: 6.7% scored 11+ 11.1% scored 8-11 82.2% scored <8	
		No control group	Partners N=135 Partners mean age=70.5		HADS depression subscale: 3.7% scored 11+ 4.4% scored 8-11 91.9% scored <7	
			Power not stated			
					Partners Mean HADS anxiety=7.2 Mean HADS depression=3.6	
					HADS anxiety subscale: 20.7% scored 11+ 28.1% scored 8-11 51.1% scored <8	
					HADS depression subscale: 3.0% scored 11+ 7.4% scored 8-11 89.6% scored <7	

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Ene, Nordberg, Johansson & Sjöström, 2006	27	Prospective No groups	N=140 Mean age=63.1 Range=43-73 Power not stated	HADS, VAS 0-100, SF-36  2 assessment points-- baseline & 3 months post-radical prostatectomy (RP)	<p>Patients</p> <p>Mean sex worries score=2.1 Above HADS cut off=65% Below HADS cut off=45% (% reporting sex worries)</p> <p>Baseline Mean HADS anxiety=5.0 Mean HADS depression=3.0</p> <p>HADS anxiety subscale: 7% scored 11+ 16% scored 8-10 77% scored &lt;8</p> <p>HADS depression subscale: 2% scored 11+ 8% scored 8-10 89% scored &lt;8</p> <p>3 Months Post RP Mean HADS anxiety=3.0 Mean HADS depression=2.6</p> <p>HADS anxiety subscale:</p>	

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Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Hervouet, Savard, Simard, Ivers, Laverdiere, Vigneault, Fradet & Lacombe, 2005	33	Cross-sectional	N=861	HADS, Insomnia Severity Index, Multidimensional Fatigue Index, EORTCQLQ-C30 & PCSM	5% scored 11+	Groups not matched
					3% scored 8-10	
					92% scored <8	
Psychological functioning associated with prostate cancer: Cross-sectional comparison of patients treated with radiotherapy, brachytherapy, or surgery		3 groups: Radiotherapy (RAD), Brachytherapy (BR) and surgery/ Radical Prostatectomy (RP)	RAD N=392 Mean age= 70.7		HADS depression subscale: 2% scored 11+ 7% scored 8-10 91% scored <8	
					HADS anxiety subscale (% scoring 7+): Whole sample=23.7% RAD=23.5% BR=23.4% RP24.2%	
					HADS depression subscale (% scoring 7+): Whole sample=17% RAD=20.9% BR=16% RP=12.1%	
No control group					Total HADS scores (% scoring 15+): Whole sample=14.6% RAD=16.3% BR=13.3% RP=13.2%	

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Korfage, Essink-Bot, Janssens, Schroder & de Koning, 2006	30	Prospective 4 groups: Prostatectomy (RP) or Radiotherapy (RAD), plus high (HA) or low anxiety (LA)	N=299 RP N=118 Mean age=62.6 Range=50-75 RAD N=181 Mean age=68.1 Range=50-82 Power not stated	STAI, CES-D, SF-36 4 Assessment points : pretreatment, 6 months, 12 months & 5 years	Sexual Dysfunction (% above clinically significant cut off) Whole sample=70.5% RAD=75.8% BR=57.3% RP=85.7%	Data not provided for prevalence of depression
Anxiety and depression after prostate cancer diagnosis and treatment: 5-year follow-up					Clinically significant levels of anxiety on STAI: Whole sample=28%, RP=25%, RAD=30% Clinically significant levels of depression on CES-D	
Lintz, Moynihan, Steginga, Norman, Eeles, Huddart, Dearnaley & Watson, 2003	28	Cross-sectional No groups	N=210 Mean age=69.7 Range=43-92	EORTCQLQ-C30 & PCSM, HADS, Support Care Needs Survey (SCNS),	Mean HADS anxiety score=4.2 Mean HADS depression score=3.4 HADS anxiety subscale:	

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Prostate cancer patients' support and psychological care needs: Survey from a non-surgical oncology clinic			Power not stated	Support Care Preferences Questionnaire (SCPQ),	<p>2% scored 11+</p> <p>12.3% scored 8-10</p> <p>85.7% scored &lt;8</p> <p>HADS depression subscale:</p> <p>1.4% scored 11+</p> <p>7.2% scored 8-10</p> <p>91.4% scored &lt;8</p> <p>SCNS (% reporting some need)</p> <p>Lost manhood=35%</p> <p>Sexual feelings=41%</p> <p>Sexual relns=36%</p> <p>PCSM</p> <p>Erection probs=78%</p> <p>Ejaculation probs=68%</p> <p>Intimacy probs=57%</p> <p>Enjoyed sex=89%</p> <p>65 or less</p> <p>Sexual interest=84%</p> <p>Sexually active=70%</p> <p>65+</p> <p>Sexual interest=45%</p> <p>Sexually active=11%</p>	

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Rosenfeld, Roth, Gandhi & Penson, 2004  Differences in health-related quality of life of prostate cancer patients based on stage of cancer	24	Cross-sectional  3 groups: localised (Loc), locally advanced (LA) and metastatic (Met)	N=341  Mean age=71.2 Range=40-93  Loc N=186 LA N=92 Met N=63  No control group  Power not stated	FACT-P, HADS, Urinary Function  Subscale of UCLA-PCI	Loc: Mean HADS anxiety=10.62 Mean HADS depression =12.02 Mean HADS total=22.64  LA: Mean HADS anxiety=10.16 Mean HADS depression =12.27 Mean HADS total=22.43  Met: Mean HADS anxiety=11.01 Mean HADS depression =12.65 Mean HADS total=23.65	
Roth, Kornblith, Batel-Copel, Peabody, Scher & Holland, 1998  Rapid screening for psychologic distress in men with prostate carcinoma	19	Cross-sectional  No groups	N=93  Mean age=71 Range=52-88  Power not stated	HADS, Distress Thermometer	HADS anxiety subscale (% scoring 7+) = 32.6%  HADS depression subscale (% scoring 7+) = 15.2%  Total HADS scores (% scoring 15+) = 13%	
Sharpley & Christie, 2007	22	Cross-sectional	N=183	Self-Rating Anxiety	At Diagnosis:	



**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Actual change in anxiety and depression among Australian men with prostate cancer		No groups	Mean age=69.2 Range=54-81  Power not stated	Scale (SAS), Self-Rating Depression Scale (SDS)	Mean SAS score=31.42 Mean SDS score=34.10  SAS - 20.2% scored 36+ SDS - 23.9% scored 40+	
					Now: Mean SAS score=29.32 Mean SDS score=31.27	
					SAS - 12.6% scored 36+ SDS - 12.6% scored 40+	
Soloway, Soloway, Kim & Kava, 2005	22	Cross-sectional	N=103	Beck Depression Inventory (BDI), Profile of Mood States (POMS), Brief Index of Sexual Function for Women (BISF-W), Brief Sexual Function Questionnaire for Men (BSFQ), Sexual Adjustment Questionnaire (SAQ), VAS 0-100, Dyadic Adjustment	Patients Mean BDI score=5.63 Mild-moderate=26.2% Moderate-severe=2% Severe=0  Mean POMS anxiety score=9.41	
Sexual, psychological and dyadic qualities of the prostate cancer 'couple'		2 groups – patient and partner  No control group	Patients N=103 Patients mean age=62 Range=43-80  Partners N=103 Partners mean age=58 Range=34-78  Power not stated		Partners Mean BDI score=8.13 Mild-moderate=19.2% Moderate-severe=10.2% Severe=2.2%  Mean POMS anxiety score=11.69	

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
				Scale (DAS), Sociodemographic Questionnaire (SQ)	Patients Mean SAQ score=5.63 Mean BSFQ score=26.2%	
					Patients Mean BSFQ Scores: Activity/performance=36.58 Satisfaction=7.25 Interest=5.89	
					Controls Mean BSFQ Scores: Activity/performance=36.8 Satisfaction=13.7 Interest=9.2	
					Partners Mean SAQ score=8.13 Mean BISF-W score=19.2%	
					Partners Mean BISF-W Scores: Thought/desires=3.67 Arousal=3.61 Freq of activity=3.9 Receptivity/initiation=9.96 Pleasure=2.74 Reln satisfaction=5.24 Probs affecting function=5.36	

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

Author/Year/Title	Score	Design	Sample	Outcome Measures	Prevalence of Anxiety, Depression & Sexual Dysfunction	Additional Comments
Steineck, Helgesen, Adolfson, Dickman, Johansson, Norlen & Holmberg, 2002	29	Cross-sectional	N=326	STAI, CES-D, other questionnaire developed for study	Controls Mean BISF-W Scores: Thought/desires=5.31 Arousal=6.21 Freq of activity=3.9 Receptivity/initiation=8.85 Pleasure=4.91 Rein satisfaction=8.9 Probs affecting function=4.47	
Quality of life after radical prostatectomy or watchful waiting		2 groups: prostatectomy (RP) and watchful waiting (WW)	RP N=166 Mean age=68.3 Range=48-74  WW N=160 Mean age=68.9 Range=51-74		RP: CES-D=7% STAI=9% (above 90th percentile)  WW: CES-D=11% STAI=10% (above 90th percentile)	
			Power not stated		RP: Sexual dysfunction=80% Distress about decline=56%  WW: Sexual dysfunction=45% Distress about decline=40%	

**Table 1 – Summary Table of Studies Addressing Anxiety and Depression in Prostate Cancer Patients including design, sample characteristics, outcome measures and main findings**

**Key**

**HADS** (Hospital Anxiety and Depression Scale),

**STAI** (State Trait Anxiety Inventory),

**FACT-P** (Functional Assessment of Cancer Therapy-Prostate Instrument),

**UCLA-PCI** (UCLA Prostate Cancer Index),

**CES-D** (Centre for Epidemiological Studies Depression Scale),

**SF-36** (36-item Short-Form Health Survey),

**EORTCQLQ-C30** (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire),

**PCSM** (Prostate Cancer Specific Module),

**VAS 0-100** (Visual Analogue Scale).

### **Chapter 3: Major Research Project Proposal**

Life After Treatment for Prostate Cancer:

Levels of Anxiety, Depression, and Sexual Dysfunction.

Prepared in accordance with guidelines for 'major research project proposal' in

Doctorate of Clinical Psychology Research Training Folder

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Clinical Psychology

## Title

Life After Treatment for Prostate Cancer: Levels of Anxiety, Depression, and Sexual Dysfunction.

## Summary

Prostate cancer affects over thirty thousand men per year in the United Kingdom (Cancer Research UK, 2005). Being diagnosed with and treated for prostate cancer involves a complex set of biological and psychological factors. Men who are treated for prostate cancer and survive often face many treatment specific side effects afterwards (Weber & Sherwill-Navarro, 2005). The side effect that is reported to be most common and cause most distress is sexual dysfunction (Matthew et al., 2005; Baker et al., 2005). Many studies have reported these problems, and acknowledged that sexual dysfunction has both physical and psychological aspects (Rosing & Berberich, 2004). More specifically studies have reported that patients have sexual problems, and have clinically significant levels of anxiety and depression (Hervouet et al., 2005) This study aims to assess levels of anxiety, depression and sexual dysfunction in men following treatment for prostate cancer. It is hypothesised that men with higher levels of sexual dysfunction will report higher levels of anxiety and depression. The study also aims to examine how coping style, quality of life, and perception of illness are related to each other and to levels of anxiety, depression, and sexual dysfunction.

## Introduction

Prostate cancer is one of the most common cancers, affecting approximately 30,100 men every year in the United Kingdom (Cancer Research UK, 2005).

Being diagnosed with and treated for prostate cancer involves a series of different medical procedures. Various psychological problems may arise at different stages in this process.

### *Symptoms of Prostate Cancer*

Men who have prostate cancer may experience: problems urinating, pain in genitals and upon ejaculation, erection difficulties, pain in the lower back and in hips or pelvis, and blood in the urine.

### *Diagnosing Prostate Cancer*

If prostate cancer is suspected a blood sample will be sent to a laboratory to test for Prostate Specific Antigen (PSA). A PSA test cannot detect prostate cancer but raised PSA levels can indicate prostate problems. A second way of diagnosing a prostate problem is to feel the prostate gland through the wall of the rectum; a Digital Rectal Examination (DRE). After these initial tests patients may be reassured that they do not have prostate cancer. Alternatively further testing can confirm a diagnosis of prostate cancer.

### *Further Diagnostic Tests*

A Trans-Rectal Ultra Sound (TRUS) Biopsy will reveal if cancerous cells are present. If a diagnosis of prostate cancer is made, more tests to find out whether it has spread will be necessary e.g. CT, MRI and bone scans.

### *Treatment Options for Prostate Cancer*

Possible treatment options for prostate cancer include: external beam radiotherapy – where radiation is used to kill cancer cells; surgery – where the prostate gland is removed; hormone therapy – where testosterone production is

altered; brachytherapy – where radioactive seeds are implanted into the prostate, or active monitoring where the state of the cancer is closely observed and treatment started if necessary.

### *Life After Treatment*

All prostate cancer treatments involve varying degrees of medical intervention. These interventions range from four hours of major surgery under a general anaesthetic to regular check ups and PSA tests (active monitoring). Surgery, radiotherapy, brachytherapy and hormone therapy are all effective in the treatment of prostate cancer but have associated side effects. Side effects include: urinary incontinence, sexual dysfunction, bowel problems, hot flushes (Engstrom, 2005), breast swelling and tenderness, weight gain and osteoporosis. Certain side effects are only caused by one particular treatment e.g. breast swelling is commonly seen in men having hormone therapy to treat their prostate cancer. Urinary incontinence and sexual dysfunction are caused by all four of the treatments described above. Urinary incontinence can range from a few drops leaking out to total lack of control, and can be acute or chronic. Sexual dysfunction includes: loss of libido, infertility, erectile dysfunction, inability to orgasm, etc.

### *Sexual Dysfunction*

Matthew et al. (2005) reviewed the literature related to sexual dysfunction following radical prostatectomy from 1966 to 2004. They found that several studies reported that 44% to 75% of men experienced sexual dysfunction, of whom more than 60% experienced distress because of their sexual dysfunction problems. This review highlighted the need for a broader perspective of sexual



dysfunction emphasizing factors such as: perceptions of inadequacy, anxieties in regard to performance and depression in each member of the couple, overly enthusiastic expectations, partner's physical and emotional readiness to resume active sex and the quality of the nonsexual relationship of the couple. This review also pointed out the need to explore the role of resumed satisfying sexuality in overall quality of life following treatment. Rosing and Berberich (2004) also support the idea that sexual dysfunction has psychological and physical components. Tan, Waldman and Bostick (2002) found that cancer and its treatment often led to disruptions in family and social relationships, and that sexual relationships were most disrupted.

Once patients have been treated for prostate cancer they will be followed up for a number of years to monitor their physical progress. Weber and Sherwill-Navarro (2005) reviewed 30 years of research on the 'psychosocial consequences' of prostate cancer. They stated that 'survivorship' in prostate cancer patients is commonly complicated by long-term disease-specific side effects, such as; sexual and urinary dysfunction. Studies have shown that the psychological impact of prostate cancer continues long after the diagnosis and treatment phases have been completed. Baker, Denniston, Smith and West (2005) used the Cancer Problems in Living Scale (CPILS) to assess 752 patients, 97 of whom had prostate cancer. They found that a year on from diagnosis: 68% of patients were concerned about their illness returning, 58% had fears about the future, and 41% reported sexual dysfunction as a major concern. However, this study did not look at the association between the level of sexual dysfunction and psychological problems. The study also had

methodological problems due to a low rate of consent to take part, resulting in limited generalizability of the findings.

### *Anxiety, Depression and Sexual Dysfunction*

Many studies have reported that cancer and psychological problems, such as anxiety and depression, often co-occur (Tan, Waldman & Bostick, 2002).

General theoretical psychological models of why people may experience anxiety and depression have been used in relation to cancer patients (Noyes et al., 1998; Massie et al., 1998). Models of Post-traumatic Stress Disorder have also been used to explain some of the psychological symptoms that people experience following a diagnosis of cancer and subsequent treatment (Smith et al., 1999).

Manzanera et al. (2003) assessed a sample of 54 patients with various types of cancer using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). They found that 32% reported depressive disorders and 30% anxiety disorders. Kollner, Lautenschlager and Pajonk (2004) reported in their review paper that the frequency of co-occurrence is approximately 50% and that depression, anxiety and possibly post-traumatic stress disorder are the problems most relevant in prostate cancer. Hervouet et al. (2005) stated that few studies have evaluated the prevalence of anxiety and depression in prostate cancer patients. They assessed 861 patients with prostate cancer using HADS, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and a supplementary Prostate Cancer-Specific Module (PCSM). Hervouet et al. (2005) found that sexual difficulties were most frequently reported (70.5%), with anxiety at 23.7% and

depression at 17%. Roth et al. (1998) assessed 93 men with prostate cancer using the HADS, and found that 32.6% scored at or above the HADS anxiety cut-off and 15.2% scored at or above the depression cut-off. These studies did not examine the association between levels of sexual dysfunction and levels of anxiety and depression.

Bez et al. (2005) examined levels of anxiety and depression in prostate cancer patients with and without sexual dysfunction. They assessed 80 men using the HADS, the Short Form-36 Quality of Life Scale (SF-36) and the Arizona Sexual Experience Scale (ASEX; McGahuey et al., 2000). They reported that 69% of patients sampled did experience sexual dysfunction following treatment for prostate cancer. They also found that men with sexual dysfunction had higher levels of depression and a lower quality of life than men who did not have any sexual dysfunctions. No significant differences were found in levels of anxiety for prostate cancer patients with or without sexual dysfunction. This study has yet to be published and has not been peer reviewed; therefore, any findings must be treated with caution until full methodological details are available.

Other studies have reported certain factors that are associated with psychological distress when being diagnosed and treated for prostate cancer. Balderson and Towell (2003) assessed 94 men with various stages of prostate cancer using the HADS and the Functional Assessment of Cancer Therapy-Prostate Instrument (FACT-P). They found that 38% of patients scored at or above the HADS cut-off score for anxiety and depression. They also reported that a multivariate regression analysis revealed that social well being, physical well-being and functional well-being were significant inverse predictors of

psychological distress. They recommended that Health Professionals should be aware of the potential for psychological distress in patients exhibiting poor physical functioning and those with apparent deficits in social or family support. This study did not look at sexual function alone, but instead as part of a more general 'health related quality of life' measure, which considered a number of physical factors. Balderson and Towell (2003) recommended that future studies may find useful information by looking at certain dimensions of 'health related quality of life' in isolation, sexual function being one of these dimensions.

Schnoll, Knowles and Harlow (2002) looked at the psychosocial, clinical and demographic correlates of adjustment to cancer. Positive psychosocial factors included: higher levels of social support, optimism, meaning in life, and lower levels of avoidant-type coping. They found that positive clinical and demographic factors included; being married, higher income, higher level of education and a positive perception of their own health. One way of assessing perception of health would be to use the Illness Perception Questionnaire - Revised (Moss-Morris et al., 2002), which has been used with cancer patients (Scharloo et al., 2005). Scharloo et al. (2005) found that illness perceptions were significantly related to quality of life; patients who perceived themselves to have better health had better quality of life. None of these studies examined factors associated with psychological distress in the context of sexual dysfunction.

Roesch et al. (2005) reviewed 33 studies, a total of 3133 men with prostate cancer, to assess the relationship between coping style and adjustment. They found that men with prostate cancer who used approach, problem-focused, and

emotion-focused coping were healthier psychologically and physically. However, Men with prostate cancer who used avoidance type coping experienced more negative psychological adjustment and worse physical health. Mehta, Lubeck, Pasta and Litwin (2003) assessed 519 men with prostate cancer from the CaPSURE (Cancer of the Prostate Strategic Urologic Research Endeavour) registry. They used the RAND 36 item Health Survey and the UCLA Prostate Cancer Index to look at health related quality of life. Following a multivariate linear regression analysis they found that there was an association between general health, mental health and fear of cancer recurrence; patients with good general and mental health were less fearful.

The need for a better understanding of patient's psychological needs at various stages has been highlighted (e.g. Matthew et al., 2005). Bez et al. (2005) proposed that further investigation into the psychological aspects of sexual dysfunction in prostate cancer patients is necessary in order to meet patient needs. As yet no study has examined the association between level of sexual dysfunction and levels of anxiety and depression. This study would add to previous knowledge regarding the psychological needs of men following treatment for prostate cancer. This in turn may assist the decisions made regarding the provision of psychological services for prostate cancer patients. In addition, looking at other factors associated with psychological distress in prostate cancer patients experiencing sexual dysfunction may assist clinicians in identifying patients who may be more 'at risk' of high levels of anxiety and depression, and allow them to intervene at an early stage in the treatment process.

## Aims & Hypotheses

### i) Aims

This study aims to investigate levels of anxiety, depression and sexual dysfunction in men following various treatments for prostate cancer. The primary objectives of this study are to:

- Assess the self-reported level of sexual dysfunction,
- Assess the self-reported level of anxiety,
- Assess the self-reported level of depression,
- Examine any relationship between level of sexual dysfunction and levels of anxiety and depression.

The secondary objectives are to:

- Identify coping style,
- Assess 'Illness perceptions',
- Assess 'Health Related Quality of Life',
- Examine the relationship between coping style and perception of illness and the level of sexual dysfunction and levels of anxiety and depression.
- Examine the relationship between health related quality of life and level of sexual dysfunction and levels of anxiety and depression.

### ii) Hypotheses

It is hypothesized that levels of anxiety and depression will be related to the level of sexual dysfunction. The dependent variables in this study will be: level of anxiety and level of depression. Independent variables that will be

investigated include: level of sexual dysfunction, coping style, illness perceptions; and 'Health Related Quality of Life'.

Following various studies and reviews of the literature (Matthew et al. 2005; Hervouet et al., 2005; Bez et al., 2005) it is predicted that:

- 1) Men with higher levels of sexual dysfunction will report higher levels of anxiety and depression.

Schnoll, Knowles and Harlow (2002) reported an association between lower levels of avoidant type coping and a positive adjustment to cancer. Roesch et al. (2005) reviewed the literature and concluded that men who used avoidance type coping experienced worse psychological and physical health. Therefore, it is predicted that:

- 2) Men who have lower levels of avoidance type coping will have lower levels of anxiety and depression.

Following the work of Schnoll, Knowles and Harlow (2002), who found that men with a positive perception of their own health had a more positive adjustment to cancer, it is predicted that:

- 3) Men who perceive themselves to have higher levels of illness will have higher levels of anxiety and depression.

Mehta, Lubeck, Pasta and Litwin (2003) found that there was an association between general health, mental health and fear of cancer recurrence; patients with good general and mental health were less fearful. Therefore, it is hypothesised that:

4) Men who report higher levels of 'health related quality of life' will have lower levels of anxiety and depression.

### Plan of Investigation

#### i) Participants

Participants will be recruited from patients attending Urology or Urooncology out-patient clinics in North Glasgow. More specifically, participants will be patients who are being followed-up after being diagnosed with and treated for prostate cancer.

#### ii) Recruitment

Permission has been given by the Urology and Urooncology Services to recruit patients attending Urology and Urooncology clinics on an outpatient basis.

Patient information sheets, two consent forms and five questionnaires will be put into sealed envelopes by the Chief Investigator. These envelopes will then be given out by Clinical Nurse Specialists to patients who attend Urology or Urooncology out-patient clinics in North Glasgow. Patients who would like to participate will then be able to complete the questionnaires in their own time and return them by post to the Chief Investigator at the Section of Psychological Medicine, Gartnavel Hospital.

#### iii) Measures

### Anxiety and Depression

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is a 14-item self-report scale, which is made up of two 7-item subscales that measure anxiety and depression. People are asked to rate each item on a 3



point scale, ranging from the absence of a symptom (0), to the maximum symptoms (3); therefore the higher the score, the higher the anxiety or depression. Reliability coefficients for the sub-scales on the HADS (Cronbach's alpha) were 0.76 for the anxiety sub-scale and 0.60 for the depression sub-scale, indicating satisfactory internal reliability (Zigmond & Snaith, 1983).

### Quality of Life

The RAND SF-36 v2 plus the UCLA Prostate Cancer Index will be used to assess 'Health Related Quality of Life'.

The RAND 36-Item Health Survey (Hays et al., 1993) assesses 'Health Related Quality Of Life' in eight domains, namely: Physical functioning, role limitations due to physical health problems, role limitations due to emotional problems, vitality, mental health, social functioning, bodily pain, general health and health transition.

The UCLA Prostate Cancer Index (Litwin et al., 1998) assesses disease-specific 'Health Related Quality Of Life' in six domains that are of particular relevance to men treated for prostate cancer. The six domains are: Urinary function, bowel function, sexual function, urinary bother, bowel bother and sexual bother.

### Sexual Dysfunction

The Arizona Sexual Experiences Scale (ASEX) will be used to assess level of sexual dysfunction (McGahuey et al., 2000). The ASEX is a five item self-report scale that quantifies: sex drive, arousal, penile erection, ability to reach orgasm,

and satisfaction from orgasm. Each of these items is measured on a 6 point Likert scale, ranging from 1 'hyperfunction' to 6 'hypofunction'. Total scores can range from 5 to 30, with higher scores indicating a higher level of sexual dysfunction.

For the purposes of this study patients who have a total score of 19 or more, score a 5 or 6 on any one item, or score a 4 or more on any three items, will be regarded as having sexual dysfunction (McGahuey et al., 2000). Satisfactory psychometric properties of the ASEX have been described by McGahuey et al. (2000), internal reliability was good (Cronbach's  $\alpha = 0.9055$ ).

### Coping Style

Coping style data will be collected using the Brief COPE-B (Carver, 1997). The COPE-B has 14 subscales: active coping, planning, positive reframing, acceptance, humour, religion, using emotional support, using instrumental support, self-distraction, denial, venting, substance abuse, behavioural disengagement, self-blame. Each of these subscales has two parts, making a total of 28 items. These items are rated from 0 'I haven't been doing this at all', to 3 'I've been doing this a lot'. The subscales on the COPE-B can then be grouped to give three different coping styles; problem-focussed, emotion-focussed, and dysfunctional coping (Carver et al., 1989; Coolidge et al., 2000). Reliability coefficients for the sub-scales (Cronbach's  $\alpha$ ) ranged from 0.50 to 0.90, indicating satisfactory internal reliability (Carver, 1997).

### Illness Perception Questionnaire

The Illness Perception Questionnaire-Revised (Moss-Morris et al., 2002) is a measure of patients' cognitive and emotional representations of their illness.

The first part of the questionnaire measures the illness identity dimension with a list of 14 commonly occurring prostate-specific symptoms. Patients are asked to rate if they have experienced each symptom since their illness and if they believe the symptom to be specifically related to their illness (yes or no). The yes-rated items form the illness identity scale; with higher scores indicating a stronger belief that the symptoms are part of the patient's illness.

The second part of the IPQ-R consists of 38 statements using 5-point Likert scales; ranging from 'strongly agree' to 'strongly disagree'. It provides separate scores for the consequences, timeline, control, illness coherence, and emotional representations scales. High scores indicate stronger beliefs in serious consequences of the disease, a chronic long-term disease, illness and/or symptoms as cyclical in nature, the patients' own ability to control symptoms, and the effectiveness of treatment in controlling the illness. Higher scores on the illness coherence scale indicate a higher degree to which patients believe they have a coherent model of the illness, and higher scores on the emotional representations scale indicate a stronger emotional response to illness. The third part, questions about causal attributions, uses the same 5-point scale and consists of 18 items. Higher scores indicate stronger beliefs in own behaviour, chance, or aging causing the illness. Reliability coefficients for the sub-scales (Cronbach's alpha) ranged from 0.70 to 0.90, indicating satisfactory internal reliability (Moss-Morris, 2002).

#### iv) Design & Procedures

The study will use a cross sectional design. Data will be collected for a single time point for each participant. The study will use a range of measures to

gather information, namely; HADS, RAND plus UCLA-PCI, ASEX, COPE-B and IPQ-R. These measures are all self-report, and will record participants' perceptions of: their symptoms of anxiety and depression, their health related quality of life, their coping, their illness, and their sexual functioning. The associations between these variables will then be examined to allow greater understanding of the factors that contribute to psychological morbidity.

Patients will be given a sealed pack when they attend the Urology or Urooncology outpatient clinics in North Glasgow. Each pack will contain: a detailed patient information sheet explaining the purpose of the study and what will be involved, two consent forms, and five questionnaires (HADS, RAND plus UCLA-PCI, ASEX, COPE-B and IPQ-R). Patients will be asked to put their hospital number rather than their name on top of all questionnaires.

Participants who choose to complete the questionnaires will then post them back to the Chief Investigator at the Section of Psychological Medicine, Gartnavel Royal Hospital in a freepost envelope, which will be included in the pack. Patients will be asked to complete two consent forms these will then be sealed in a separate envelope and held by the Academic Supervisor (Professor Keith Millar). Professor Millar will countersign both consent forms, one will be held on file and the other will be sent back to the patient for their reference. As suggested in COREC 'Guidelines for Researchers – Information Sheets & Consent Forms' (Version 2.0 22 November 2005); "If the consent form is to be signed at home and returned by mail to the researcher, 2 copies must be provided, both to be returned and countersigned by the researcher, and one copy posted back to the participant".

#### v) Settings & Equipment

All participant correspondence will take place through Urology and Urooncology clinics, in North Glasgow.

#### vi) Power Calculation

This study will investigate two dependent variables, namely; level of anxiety and level of depression. Four independent variables will be investigated; level of sexual dysfunction, coping style, perception of illness, and health related quality of life.

According to one formula provided by Green (1991),  $N = 50 + 8m$ , where  $m$  is the number of independent variables. Therefore, for this study  $N = 50 + (8 \times 4)$ , which is 82. In line with convention the level of significance is 0.05 and power is 0.80 (Cohen, 1992). This figure is similar to the number of participants used in previous studies in this area (Balderson & Towell, 2003; Bez et al., 2005).

#### vii) Data Analysis

Data will be analysed using SPSS version 12.0.1 for windows. Initially, summary statistics will be used to describe the sample in terms of levels of anxiety, depression, and sexual dysfunction; and also coping style, illness perception, and health related quality of life. Correlational analyses will also be required to investigate the relationships between variables. Scores for anxiety and depression will be analysed both as a continuous measure and according to established cut-off points for degrees of caseness on the HADS (Zigmond & Snaith, 1994). Zigmond & Snaith (1994) recommended that, for the anxiety and depression scales, raw scores of between 8 and 10 identify mild cases, 11–15

moderate cases, and 16 or above severe cases. Finally, a regression analysis will be carried out with the HADS score as the outcome measure.

### Practical Applications

Studies have identified that the psychological needs of prostate cancer patients are often unmet (Lintz et al., 2003). It has also been reported that sexual dysfunction is the most commonly reported side-effect of treatment for prostate cancer (Herouvet et al. 2005). Studies support the idea that sexual dysfunction has both physical and psychological components (Rosing & Berberich, 2004), but currently most treatments options for sexual dysfunction are of a physical nature and are not very successful (Matthew et al., 2005). A better understanding of levels of anxiety, depression and sexual dysfunction in men with prostate cancer would add to existing information regarding the psychological components that are associated with sexual difficulties. This in turn would help to guide psychological treatment options for men with sexual dysfunction following treatment for prostate cancer. Looking at other factors associated with psychological distress in prostate cancer patients such as; coping style, illness perception, and quality of life, may assist clinicians in identifying patients who may be more 'at risk' of high levels of anxiety and depression, and allow them to intervene at an early stage in the treatment process.

### Timescale

Data collection – January 2007 to May 2007

Write up – May 2007 to July 2007

## Ethical Approval

Ethical approval will be sought from Greater Glasgow Health Board at the Glasgow West Local Research Ethics Committee meeting in December 2006.

The proposal was submitted to the In-House Trials Advisory Board (IHTAB) meeting at the Beatson Oncology Centre on 14<sup>th</sup> November 2006 (see Appendix 3.1). The project has approval from this panel to proceed to the Glasgow West Local Research Ethics Committee.

One particular ethical issue to consider is the onward referral pathway for patients who are found to have clinically significant levels of anxiety and depression. This will be clearly established and agreed with the Clinical Psychologists at the Beatson Oncology Centre. Participants who have completed questionnaires will have included their hospital number; this would allow the Chief Investigator to contact the Consultant Clinical Oncologist, Consultant Urologist or Clinical Nurse Specialist. The patient could then be offered the opportunity to see a Clinical Psychologist at the Beatson Oncology Centre if they wished to.

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## **Chapter 4: Major Research Project**

**Life After Treatment for Prostate Cancer:**

**Levels of Anxiety, Depression, and Sexual Dysfunction.**

**Prepared in accordance with requirements for submission to Psycho-Oncology  
(see Appendix 1.1).**

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**Submitted in partial fulfilment of the requirements of the degree of Doctorate in  
Clinical Psychology**

## **Title**

Life After Treatment for Prostate Cancer: Levels of Anxiety, Depression, and Sexual Dysfunction.

## **Abstract**

This study aimed to assess levels of anxiety, depression and sexual dysfunction in men following treatment for prostate cancer. It was hypothesised that men with higher levels of sexual dysfunction would report higher levels of anxiety and depression. The study also aimed to examine how coping, quality of life, and perception of illness were related to each other and to levels of anxiety, depression, and sexual dysfunction. Fifty-two participants were recruited from patients attending Urology or Uro-oncology out-patient clinics in North Glasgow. Data were collected for a single time point for each participant using six self-report measures, namely; the Hospital Anxiety and Depression Scale (HADS), the RAND SF-36 v2 plus the UCLA Prostate Cancer Index (UCLA-PCI), the Arizona Sexual Experiences Scale (ASEX), the Brief COPE questionnaire (COPE-B) and the Illness Perception Questionnaire-Revised (IPQ-R). Data were examined using correlation analyses. Significant correlations were discovered between levels of depression and levels of sexual dysfunction. Significant correlations were also found between depression scores on the HADS, specific dimensions on the COPE-B and IPQ-R, and all dimensions of health-related quality of life assessed using the SF-36. Limitations of the study, possible clinical applications and ideas for future research are discussed.

**Keywords** – Prostate, cancer, anxiety, depression, sexual dysfunction.



## **Introduction**

### *Symptoms, Diagnosis and Treatment of Prostate Cancer*

Prostate cancer is one of the most common cancers, affecting approximately 30,900 men every year in the United Kingdom [1]. Men who have prostate cancer may experience: problems urinating, pain in genitals and upon ejaculation, erection difficulties, pain in the lower back and in hips or pelvis, and blood in the urine. If prostate cancer is suspected a number of tests are required before this diagnosis can be confirmed, including PSA tests, CT, MRI and bone scans. If a diagnosis of prostate cancer is confirmed possible treatment options include: external beam radiotherapy, surgery – where the prostate gland is removed; hormone therapy, brachytherapy – where radioactive seeds are implanted into the prostate, or active monitoring where the state of the cancer is closely observed and treatment started if necessary.

### *Life After Treatment*

All prostate cancer treatments involve varying degrees of medical intervention. These interventions range from four hours of major surgery under a general anaesthetic to regular check ups and PSA tests (active monitoring). Surgery, radiotherapy, brachytherapy and hormone therapy are all effective in the treatment of prostate cancer but have associated side effects. Side effects include: urinary incontinence, sexual dysfunction, bowel problems, hot flushes, breast swelling and tenderness, weight gain and osteoporosis. Certain side effects, such as urinary incontinence and sexual dysfunction, are caused by all four of the treatments described above. Urinary incontinence can range from a few drops leaking out to total lack of control, and can be acute or chronic.

Sexual dysfunction can include; loss of libido, infertility, erectile dysfunction, and inability to orgasm.

### *Sexual Dysfunction*

Matthew et al. [2] reviewed the literature related to sexual dysfunction following radical prostatectomy from 1966 to 2004. They found that several studies reported that 44% to 75% of men experienced sexual dysfunction, of whom more than 60% experienced distress because of their sexual dysfunction problems. This review highlighted the need for a broader perspective of sexual dysfunction emphasizing factors such as: perceptions of inadequacy, anxieties in regard to performance and depression in each member of the couple, overly enthusiastic expectations, partner's physical and emotional readiness to resume active sex and the quality of the nonsexual relationship of the couple. This review also pointed out the need to explore the role of resumed satisfying sexuality in overall quality of life following treatment. Rosing and Berberich [3] also support the idea that sexual dysfunction has psychological and physical components. Tan, Waldman and Bostick [4] found that cancer and its treatment often led to disruptions in family and social relationships, and that sexual relationships were most disrupted.

Once patients have been treated for prostate cancer they will be followed up for a number of years to monitor their physical progress. Weber and Sherwill-Navarro [5] reviewed 30 years of research on the 'psychosocial consequences' of prostate cancer. They stated that 'survivorship' in prostate cancer patients is commonly complicated by long-term disease-specific side effects, such as; sexual and urinary dysfunction. Studies have shown that the psychological

impact of prostate cancer continues long after the diagnosis and treatment phases have been completed. Baker, Denniston, Smith and West [6] used the Cancer Problems in Living Scale (CPILS) to assess 752 patients, 97 of whom had prostate cancer. They found that a year on from diagnosis: 68% of patients were concerned about their illness returning, 58% had fears about the future, and 41% reported sexual dysfunction as a major concern. However, this study did not look at the association between the level of sexual dysfunction and psychological problems. The study also had methodological problems due to a low rate of consent to take part, resulting in limited generalizability of the findings.

#### *Anxiety, Depression and Sexual Dysfunction*

Many studies have reported that cancer and psychological problems, such as anxiety and depression, often co-occur [4]. General theoretical psychological models of why people may experience anxiety and depression have been used in relation to cancer patients [7, 8]. Models of Post-traumatic Stress Disorder have also been used to explain some of the psychological symptoms that people experience following a diagnosis of cancer and subsequent treatment [9].

Manzanera et al. [10] assessed a sample of 54 patients with various types of cancer using the Hospital Anxiety and Depression Scale [11]. They found that 32% reported depressive disorders and 30% anxiety disorders. Kollner, Lautenschlager and Pajonk [12] reported in their review paper that the frequency of co-occurrence is approximately 50% and that depression, anxiety and possibly post-traumatic stress disorder are the problems most relevant in

prostate cancer. Hervouet et al. [13] stated that few studies have evaluated the prevalence of anxiety and depression in prostate cancer patients. They assessed 861 patients with prostate cancer using HADS, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and a supplementary Prostate Cancer-Specific Module (PCSM). Hervouet et al. [13] found that sexual difficulties were most frequently reported (70.5%), with anxiety at 23.7% and depression at 17%. Roth et al. [14] assessed 93 men with prostate cancer using the HADS, and found that 32.6% scored at or above the HADS anxiety cut-off and 15.2% scored at or above the depression cut-off. These studies did not examine the association between levels of sexual dysfunction and levels of anxiety and depression.

Bez et al. [15] examined levels of anxiety and depression in prostate cancer patients with and without sexual dysfunction. They assessed 80 men using the HADS, the Short Form-36 Quality of Life Scale (SF-36) and the Arizona Sexual Experience Scale [16]. They reported that 69% of patients sampled did experience sexual dysfunction following treatment for prostate cancer. They also found that men with sexual dysfunction had higher levels of depression and a lower quality of life than men who did not have any sexual dysfunctions. No significant differences were found in levels of anxiety for prostate cancer patients with or without sexual dysfunction. This study has yet to be published and has not been peer reviewed; therefore, any findings must be treated with caution until full methodological details are available.

Other studies have reported certain factors that are associated with psychological distress when being diagnosed and treated for prostate cancer. Balderson and Towell [17] assessed 94 men with various stages of prostate cancer using the HADS and the Functional Assessment of Cancer Therapy-Prostate Instrument (FACT-P). They found that 38% of patients scored at or above the HADS cut-off score for anxiety and depression. They also reported that a multivariate regression analysis revealed that social well being, physical well-being and functional well-being were significant inverse predictors of psychological distress. They recommended that Health Professionals should be aware of the potential for psychological distress in patients exhibiting poor physical functioning and those with apparent deficits in social or family support. This study did not look at sexual function alone, but instead as part of a more general 'health related quality of life' measure, which considered a number of physical factors. Balderson and Towell [17] recommended that future studies may find useful information by looking at certain dimensions of 'health related quality of life' in isolation, sexual function being one of these dimensions.

Schnoll, Knowles and Harlow [18] looked at the psychosocial, clinical and demographic correlates of adjustment to cancer. Positive psychosocial factors included: higher levels of social support, optimism, meaning in life, and lower levels of avoidant-type coping. They found that positive clinical and demographic factors included; being married, higher income, higher level of education and a positive perception of their own health. One way of assessing perception of health would be to use the Illness Perception Questionnaire - Revised [19], which has been used with cancer patients [20]. Scharloo et al. [20] found that illness perceptions were significantly related to quality of life;

patients who perceived themselves to have better health had better quality of life. None of these studies examined factors associated with psychological distress in the context of sexual dysfunction.

Roesch et al. [21] reviewed 33 studies, a total of 3133 men with prostate cancer, to assess the relationship between coping style and adjustment. They found that men with prostate cancer who used approach, problem-focused, and emotion-focused coping were healthier psychologically and physically. However, men with prostate cancer who used avoidance type coping experienced more negative psychological adjustment and worse physical health. Mehta, Lubeck, Pasta and Litwin [22] assessed 519 men with prostate cancer from the CaPSURE (Cancer of the Prostate Strategic Urologic Research Endeavour) registry. They used the RAND 36 item Health Survey and the UCLA Prostate Cancer Index to look at health related quality of life. Following a multivariate linear regression analysis they found that there was an association between general health, mental health and fear of cancer recurrence; patients with good general and mental health were less fearful.

The need for a better understanding of patient's psychological needs at various stages has been highlighted [2]. Bez et al. [15] proposed that further investigation into the psychological aspects of sexual dysfunction in prostate cancer patients is necessary in order to meet patient needs. As yet no study has examined the association between level of sexual dysfunction and levels of anxiety and depression. This study would add to previous knowledge regarding the psychological needs of men following treatment for prostate cancer. This in turn may assist the decisions made regarding the provision of psychological

services for prostate cancer patients. In addition, looking at other factors associated with psychological distress in prostate cancer patients experiencing sexual dysfunction may assist clinicians in identifying patients who may be more 'at risk' of high levels of anxiety and depression, and allow them to intervene at an early stage in the treatment process.

The aims of the current study were to investigate levels of self-reported anxiety, depression and sexual dysfunction in men following various treatments for prostate cancer. The study also aimed to examine any relationship between level of sexual dysfunction and levels of anxiety and depression. Secondary objectives were to assess coping, illness perceptions and health related quality of life, and to explore any relationships between these factors and levels of anxiety, depression and sexual dysfunction. It was hypothesized that men with higher levels of sexual dysfunction would report higher levels of anxiety and depression. It was also predicted that men who had lower levels of avoidance type coping would have lower levels of anxiety and depression, and that men who perceived themselves to have higher levels of illness would have higher levels of anxiety and depression. Finally it was hypothesised that men who reported higher levels of 'health related quality of life' would have lower levels of anxiety and depression.

## **Method**

Fifty-two participants were recruited from patients attending Urology or Uro-oncology out-patient clinics in North Glasgow. Inclusion criteria stated that participants must be aged 16 years or older, and have received a diagnosis of prostate cancer and received treatment. Participants were recruited from those

who are 'relatively stable, follow-up' cases. 'Relatively stable' was defined as at least 3 months post diagnosis and initial treatment. Patients who could not understand written English were excluded from the study due to the self-report design of the questionnaires. Patients who were suffering from any other life-threatening illnesses were also excluded due to the high levels of distress this may cause. Ethical approval was obtained from the Glasgow West Local Research Ethics Committee meeting in February 2007 (see Appendix 4.1).

Questionnaire packs were compiled by the Chief Investigator and distributed by Clinical Nurse Specialists at Urology or Uro-oncology outpatient clinics.

Patients were given sealed packs containing: a detailed patient information sheet explaining the purpose of the study and what would be involved (Appendix 4.2), two consent forms (Appendix 4.3), and five questionnaires (Appendix 4.4). Patients were asked to put their hospital number rather than their name on top of all questionnaires. Participants who chose to complete the questionnaires then posted them back to the Chief Investigator in a freepost envelope, which was included in the pack. Patients were asked to complete two consent forms and seal them in a separate envelope. A second member of the research team countersigned both consent forms, one was held on file and the other was sent back to the patient for their reference with a standard letter thanking them for their participation (Appendix 4.5). As suggested in COREC 'Guidelines for Researchers – Information Sheets & Consent Forms' (Version 2.0 22 November 2005); "If the consent form is to be signed at home and returned by mail to the researcher, two copies must be provided, both to be returned and countersigned by the researcher, and one copy posted back to the participant".



## Measures

The Hospital Anxiety and Depression Scale [11] is a 14-item self-report scale, which is made up of two 7-item subscales that measure anxiety and depression. Reliability coefficients for the sub-scales on the HADS (Cronbach's alpha) were 0.76 for the anxiety sub-scale and 0.60 for the depression sub-scale, indicating satisfactory internal reliability [11].

The RAND SF-36 v2 plus the UCLA Prostate Cancer Index was used to assess 'Health Related Quality of Life'. The RAND 36-Item Health Survey [23] assesses 'Health Related Quality Of Life' in nine domains, namely: Physical functioning, role limitations due to physical health problems, role limitations due to emotional problems, vitality, mental health, social functioning, bodily pain, general health and health transition. Demographic information including; age, ethnic background, relationship status, education, employment, was also collected using the questionnaire.

The UCLA Prostate Cancer Index [24] assesses disease-specific 'Health Related Quality Of Life' in six domains that are of particular relevance to men treated for prostate cancer. The six domains are: Urinary function, bowel function, sexual function, urinary bother, bowel bother and sexual bother.

The Arizona Sexual Experiences Scale (ASEX) was used to assess level of sexual dysfunction [16]. The ASEX is a five item self-report scale that quantifies: sex drive, arousal, penile erection, ability to reach orgasm, and satisfaction from orgasm (see Appendix 4.4). Each of these items is measured

on a 6 point Likert scale, ranging from 1 'hyperfunction' to 6 'hypofunction'.

Total scores can range from 5 to 30, with higher scores indicating a higher level of sexual dysfunction. Satisfactory psychometric properties of the ASEX have been described by McGahuey et al. [16], internal reliability was good (Cronbach's  $\alpha = 0.9055$ ).

Coping style data was collected using the Brief COPE-B [25]. The COPE-B has 14 subscales: active coping, planning, positive reframing, acceptance, humour, religion, using emotional support, using instrumental support, self-distraction, denial, venting, substance abuse, behavioural disengagement, self-blame.

Each of these subscales has two parts, making a total of 28 items. These items are rated from 0 'I haven't been doing this at all', to 3 'I've been doing this a lot'.

Reliability coefficients for the sub-scales (Cronbach's  $\alpha$ ) ranged from 0.50 to 0.90, indicating satisfactory internal reliability [26].

The Illness Perception Questionnaire-Revised [19] is a measure of patients' cognitive and emotional representations of their illness. The first part of the questionnaire measures the illness identity dimension with a list of 14 commonly occurring prostate-specific symptoms. Patients are asked to rate if they have experienced each symptom since their illness and if they believe the symptom to be specifically related to their illness (yes or no). The yes-rated items form the illness identity scale; with higher scores indicating a stronger belief that the symptoms are part of the patient's illness.

The second part of the IPQ-R consists of 38 statements using 5-point Likert scales; ranging from 'strongly agree' to 'strongly disagree'. It provides separate

scores for the consequences, timeline, control, illness coherence, and emotional representations scales. High scores indicate stronger beliefs in serious consequences of the disease, a chronic long-term disease, illness and/or symptoms as cyclical in nature, the patients' own ability to control symptoms, and the effectiveness of treatment in controlling the illness. Higher scores on the illness coherence scale indicate a higher degree to which patients believe they have a coherent model of the illness, and higher scores on the emotional representations scale indicate a stronger emotional response to illness. The third part, questions about causal attributions, uses the same 5-point scale and consists of 18 items. Higher scores indicate stronger beliefs in own behaviour, chance, or aging causing the illness. Reliability coefficients for the sub-scales (Cronbach's alpha) ranged from 0.70 to 0.90, indicating satisfactory internal reliability [19].

## **Design & Procedures**

The study used a cross sectional design. Data were collected for a single time point for each participant. The study used a range of measures to gather information, namely; HADS, RAND plus UCLA-PCI, ASEX, COPE-B and IPQ-R. These measures are all self-report and recorded participants' perceptions of: their symptoms of anxiety and depression, their health related quality of life, their coping, their illness, and their sexual functioning. The associations between these variables were then examined to allow greater understanding of the factors that contribute to psychological morbidity.

The study investigated two dependent variables, namely; level of anxiety and level of depression as assessed by the HADS. Four independent variables

were investigated; level of sexual dysfunction, coping style, perception of illness, and health related quality of life. According to one formula provided by Green [27],  $N$  (the required sample size) =  $50 + 8m$ , where  $m$  is the number of independent variables. Therefore, for this study  $N = 50 + (8 \times 4)$ , which is 82. In line with convention the level of significance is 0.05 and power is 0.80 [28]. This figure is similar to the number of participants used in previous studies in this area [17, 15].

### **Data Analysis**

Data were analysed using SPSS version 14.0.1 for windows. Initially, summary statistics were used to describe the sample in terms of demographic information, levels of anxiety, depression, and sexual dysfunction; and also coping style, illness perception, and health related quality of life. Correlational analyses were also required to investigate any relationships between variables. Scores for anxiety and depression were analysed both as a continuous measure and according to established cut-off points for degrees of caseness on the HADS [29]. Zigmond & Snaith [29] recommended that, for the anxiety and depression scales, raw scores of between 8 and 10 identify mild cases, 11–15 moderate cases, and 16 or above severe cases. Caseness on the HADS anxiety and depression subscales, and levels of sexual dysfunction were also investigated for three age ranges: 55 to 65, 66 to 75, 76 or over. A regression analysis was also planned to further investigate any associations between HADS scores, sexual dysfunction, coping, illness perceptions and health-related quality of life.

## Results

One hundred and fifty questionnaire packs were distributed by Clinical Nurse Specialists at Urology or Uro-oncology outpatient clinics. Fifty-five completed packs were returned to the Chief Investigator, a 36.7% return rate. Three patients were excluded; two patients did not consent to take part in the study and one patient did not return the consent forms. Fifty-two patients were included in the study.

### *Patient Demographics*

The demographic characteristics of the 52 patients are illustrated in Table 1. The sample is described in terms of age, ethnic background, relationship status, education, and employment status.

[Insert Table 1 here]

Descriptive statistics, including mean scores, standard deviations and ranges for all outcome measures, are illustrated in Table 2.

[Insert Table 2 here]

### *Anxiety, Depression and Sexual Dysfunction*

The mean score on the HADS anxiety subscale was 5.23 (SD 4.32). Seventy-six point nine percent of patients scored below clinically significant levels for anxiety on the HADS [29]. Seven point seven percent scored between 8 and 10 (mild), 11.5% scored between 11 and 15 (moderate), and 3.9% scored 16 or more (severe). The mean score on the HADS depression subscale was 3.50 (SD 3.39). Eighty-eight point four percent of patients scored below clinically significant levels for depression on the HADS. Seven point seven percent

scored between 8 and 10 (mild), 3.9% scored between 11 and 15 (moderate), and none of the sample scored 16 or more (severe). The mean score on the ASEX was 24.21 out of 30 (SD 5.65), with higher scores indicating higher levels of sexual dysfunction. Mean scores on the UCLA PCI were 20.14 (SD 24.59) out of 100 for sexual function and 46.63 (SD 40.53) for sexual bother, with lower scores indicating lower levels of functioning.

Initially, correlation analyses were carried out to address the main research hypothesis; that men with higher levels of sexual dysfunction would report higher levels of anxiety and depression. These analyses aimed to examine any relationships between the main independent and dependent variables, namely, HADS anxiety and depression scores, and sexual dysfunction assessed using the ASEX and the UCLA PCI (sexual function and sexual bother). A significant positive correlation was found between HADS depression scores and ASEX scores ( $r=0.326$ ,  $p<0.05$ ); higher levels of depression were related to higher levels of sexual dysfunction. A significant negative correlation was discovered between HADS depression scores and UCLA PCI sexual function scores ( $r=-0.330$ ,  $p<0.05$ ), with higher levels of depression being related to lower levels of sexual functioning. No significant correlations (Pearson correlation, two-tailed) were found between HADS anxiety scores and the three measures of sexual dysfunction, or between HADS depression scores and UCLA PCI sexual bother scores.

For the 88.4% of patients who scored below clinically significant levels on the HADS depression subscale (7 or less), the mean ASEX score was 23.91 (SD 5.7), and the mean UCLA PCI sexual function score was 21.86 (SD 25.40).

Eleven point six percent of patients scored above clinically significant levels of depression (8 or more) on the HADS, the mean ASEX score for these patients was 26.5 (SD 5.05) and the mean sexual function score was 6.94 (SD 11.24).

### *Coping, Illness Perceptions, and Health Related Quality of Life*

Following on from the main research hypothesis further correlations were carried out in order to establish the nature of any relationships between HADS depression scores and coping, illness perceptions, and health related quality of life. Mean scores, standard deviations and ranges for these measures are illustrated in Table 2. Firstly, three dimensions of the COPE-B were found to be significantly correlated with HADS depression scores. The 'denial' dimension of the COPE-B was found to be positively correlated with HADS depression scores ( $r=0.369$ ,  $p<0.01$ ), with higher levels of denial being related to higher depression scores. The 'substance use' dimension of the COPE-B was found to be positively correlated ( $r=0.316$ ,  $p<0.05$ ), with higher levels of substance use being related to higher depression scores on the HADS. The 'venting' dimension of the COPE-B was also found to be positively correlated with HADS depression scores ( $r=0.486$ ,  $p<0.01$ ), with higher levels of venting being related to higher depression scores on the HADS.

The relationships between HADS depression scores and illness perceptions were also investigated. Three dimensions of the IPQ-R were found to be significantly correlated with HADS depression scores. The 'identity' dimension of the IPQ-R was found to be positively correlated with HADS depression scores ( $r=0.388$ ,  $p<0.01$ ), with higher levels of 'illness identity' being related to higher depression scores. The 'consequences' dimension of the IPQ-R was

also found to be positively correlated ( $r=0.644$ ,  $p<0.01$ ), with higher consequences of illness being related to higher depression scores on the HADS. The 'emotional representations' dimension of the IPQ-R was found to be positively correlated with HADS depression scores ( $r=0.331$ ,  $p<0.05$ ), with higher levels of negative emotions about illness being related to higher depression scores on the HADS.

The relationship between health-related quality of life and HADS depression scores was analysed using correlations. Significant negative correlations were found between depression scores and eight dimensions of health-related quality of life: physical functioning ( $r= -0.631$ ,  $p<0.01$ ), physical role limitations ( $r= -0.622$ ,  $p<0.01$ ), emotional role limitations ( $r= -0.674$ ,  $p<0.01$ ), vitality ( $r= -0.667$ ,  $p<0.01$ ), mental health ( $r= -0.716$ ,  $p<0.01$ ), social functioning ( $r= -0.518$ ,  $p<0.01$ ), bodily pain ( $r= -0.642$ ,  $p<0.01$ ), and general health ( $r= -0.628$ ,  $p<0.01$ ). Low scores on all of these dimensions indicated low quality of life, and were correlated with high levels of depression. The 'health transition' dimension was positively correlated with HADS depression scores ( $r=0.438$ ,  $p<0.01$ ), with higher scores indicating a lower quality of life.

All of the above dimensions of coping, illness perceptions and health related quality of life were also found to be significantly correlated with HADS anxiety scores. However, in the current study the relationship between sexual dysfunction and anxiety or depression is considered central. No significant relationships were discovered between HADS anxiety scores and the measures of sexual dysfunction, therefore, anxiety scores were not investigated in further depth.



It had been intended to conduct regression analyses to investigate the relationship between HADS scores and the independent variables of coping, illness perceptions, health-related quality of life, and sexual dysfunction. As described in the method section, the power and sample size calculations showed that a sample of 82 patients was required in order to provide sufficient power to conduct such a regression analysis. As the number of participants (52) fell considerably short of the required sample size, and given the marked collinearity between independent variables, it was not considered valid to proceed with regression analysis.

### *Age*

The mean age of the sample was 70.65 years, ranging from 57 years of age to 86. The sample was divided into three age groups; 65 or less (N=13), 66 to 75 (N=25) and 76 plus (N=14). Levels of anxiety and depression on the HADS and levels of sexual dysfunction were investigated for the three age groups. Means, standard deviations and ranges are displayed in Table 3.

[Insert Table 3 here]

On the HADS anxiety subscale 38.46% of men in the 65 or less group scored above the clinically significant cut-off, compared to 16% of men aged 66 to 75, and 21.43% in the 76 plus group. On the HADS depression subscale 15.38% of men in the 65 or less group scored above clinically significant levels, compared to 8% in the 66 to 75 group and 14.29% aged 76 or more. Men in the 76 plus age group had a mean score of 27.79 (SD 3.02) on the ASEX, compared to 23.36 (SD 5.79) for the 66 to 75 group, and 22 (SD 6.11) for men who were 65 or less. Men in the 76 plus group reported the lowest levels of

sexual functioning on the UCLA PCI with a mean scores of 7.22 (SD 11.38), followed by mean in the 66 to 75 group who scored 24.05 (SD 26.05). Finally, men aged 65 or less had the highest levels of sexual functioning with a mean score of 26.52 (28.33). Men aged 65 or less were most 'bothered' by their levels of sexual functioning with a mean score of 26.92 (SD 34.55), followed by men aged 76 plus who scored an average of 51.79 (SD 45.43). Men in the 66 to 75 age group reported the least 'bother' on the UCLA PCI with a mean score of 54 (SD 38.65).

Correlation analyses revealed significant correlations between age and scores on the ASEX and the UCLA PCI sexual functioning and sexual bother dimensions. Age and ASEX scores were positively correlated ( $r=0.422$ ,  $p<0.01$ ). Age and UCLA PCI scores were negatively correlated for sexual functioning ( $r= -0.332$ ,  $p<0.05$ ), with older men reporting lower levels of functioning. Age and UCLA PCI scores were positively correlated for sexual bother ( $r=0.281$ ,  $p<0.05$ ), with older men reporting less bother from their sexual problems. No significant relationships were discovered between age and anxiety or depression assessed using the HADS.

## **Discussion**

One primary aim of the current study was to investigate levels of self-reported anxiety, depression and sexual dysfunction in men following various treatments for prostate cancer. Scores for anxiety (Mean=5.23) and depression (Mean=3.50) revealed that the majority of patients were below clinically significant levels; with 23.1% of patients reporting clinically significant levels of anxiety and 11.5% reporting clinically significant levels of depression. These

prevalence rates are similar to those reported in previous studies [13]. Men reported high levels of sexual dysfunction on the ASEX with an average score of 24.21 out of 30. Mean scores on the UCLA PCI were low, (20.14 / 100) for sexual function and (46.63 / 100) for sexual bother, with lower scores indicating lower levels of functioning. Although previous studies addressing sexual problems have been limited and have reported their data in ways which make comparison problematic, it is clear that men are reporting high levels of difficulty in this area.

The study also aimed to examine any relationships between levels of sexual dysfunction and levels of anxiety and depression. It was hypothesized that men with higher levels of sexual dysfunction would report higher levels of anxiety and depression. This hypothesis was partially supported by the finding that HADS depression scores were significantly correlated with ASEX ( $r=0.326$ ,  $p<0.05$ ) and UCLA PCI sexual function scores ( $r= -0.330$ ,  $p<0.05$ ). No significant relationships were discovered between HADS anxiety scores and measures of sexual dysfunction. Mean ASEX and UCLA PCI sexual function scores for men above and below clinically significant cut-offs for HADS depression scores were reported. These scores revealed that men who were above the clinically significant cut-off for depression on the HADS reported higher levels of sexual dysfunction on the ASEX (26.5) compared to those below the cut-off (23.91). They also reported lower levels of sexual functioning on the UCLA PCI sexual function dimension, 6.94 compared to 21.86.

Secondary objectives were to assess coping, illness perceptions and health related quality of life, and to explore any relationships between these factors and levels of anxiety, depression and sexual dysfunction.

It was predicted that men who had lower levels of avoidance type coping, assessed by the COPE-B, would have lower levels of anxiety and depression. This hypothesis was partially supported by the finding that three dimensions of the COPE-B were found to be significantly correlated with HADS depression scores. The 'denial', 'substance use' and 'venting' dimensions of the COPE-B were positively correlated with HADS depression scores, with higher levels of these types of coping being related to higher depression levels. Previous studies have linked these dimensions to 'avoidant' coping and to higher levels of psychological distress [21, 18]. However, not all dimensions on the COPE-B that are considered to indicate 'avoidant' coping were found to be related to HADS depression scores. This finding may suggest that these particular dimensions are important for this population.

Illness perceptions were also investigated for this population and it was hypothesised that men who perceived themselves to have higher levels of illness would have higher levels of anxiety and depression. Three dimensions of the IPQ-R were found to be significantly positively correlated with HADS depression scores, providing partial support for this hypothesis. The 'identity', 'consequences' and 'emotional representations' dimensions of the IPQ-R were found to be positively correlated with HADS depression scores, with higher levels of negative perceptions about illness being related to higher depression scores on the HADS. Again, not all dimensions on the IPQ-R were found to be

related to HADS depression scores, suggesting that these particular dimensions may be important in prostate cancer patients.

Finally it was hypothesised that men who reported higher levels of 'health related quality of life' would have lower levels of anxiety and depression.

Significant correlations were found between HADS depression scores and all nine dimensions of health-related quality of life. These findings provided partial support for the hypothesis, in that increased levels of depression appeared to be related to lower levels of health-related quality of life.

Following these analyses the relationships between age and levels of anxiety, depression and sexual dysfunction were also investigated. On the HADS anxiety and depression sub-scales a higher percentage of men who were 65 or less scored above clinically significant cut-offs than men who were over 66 to 75, or 76 and over. Mean scores on the ASEX and UCLA PCI sexual functioning and sexual bother dimensions, and correlation analyses of these scores with age, revealed that although older men experienced higher levels of sexual dysfunction and lower levels of sexual functioning they appeared to be least 'bothered' by their sexual difficulties. Previous studies have reported that men who were 65 or less were significantly more interested in sex and more sexually active than men who were over 65 years of age [30]. This may help to explain why older men seemed to be less 'bothered' by their sexual problems and reported lower levels of anxiety and/or depression.

Correlation analyses revealed that seventeen factors were significantly correlated with HADS depression scores, namely; ASEX scores, UCLA PCI

sexual function scores, COPE-B 'denial', 'substance use' and 'venting' dimensions, IPQ-R 'identity', 'consequences' and 'emotional representations' dimensions, and all nine health related quality of life dimensions on the SF-36. Initially a regression analysis to investigate associations between HADS depression scores and these factors was planned. However, only fifty-two participants were recruited to the study resulting in insufficient numbers of participants per independent variable [27]. During data analysis it also emerged that colinearity between and within measures was a problem. All of the dimensions on the SF-36 were found to be significantly correlated with each other, and with the 'identity' and 'consequences' dimensions of the IPQ-R. These difficulties led to the conclusion that regression analyses were not appropriate in this instance.

## **Limitations**

The current study has a number of methodological limitations. Firstly, the final sample in the study consisted of 52 participants. This number was lower than the required sample size initially calculated which, for two dependent and four independent variables, was 82 participants [27].

Secondly, the response rate of 36.7% means that just under two thirds of men approached did not return their questionnaires. No information was available regarding the men who did not complete the questionnaires, making it difficult to comment on the representativeness of the sample, and therefore, the generalisability of the findings.

Thirdly, the current study used a cross-sectional design which allowed for self-report data to be collected for a single time point. In order to provide a more comprehensive picture of prostate cancer patients at different stages of treatment and follow-up it would have been preferable to use a longitudinal design. This would have allowed the researcher to examine any fluctuations of psychological distress and levels of sexual functioning throughout the prostate cancer patient's journey.

Finally, during this study men were not analysed by treatment group. The type of treatment used may have had an impact on the levels of sexual dysfunction, anxiety and depression. Previous studies have found significant differences between treatment groups when looking at levels of psychological distress [13]. However, due to the very complex nature of prostate cancer treatments and the small number of patients in this study it was not considered appropriate to analyse participants according to treatment type.

### **Future Research & Clinical Applications**

Future research may firstly aim to address some of the methodological problems described for the current study, such as, using a prospective design, recruiting a large sample, using methods that may result in an increased response rate, and analysing participants in terms of treatment group.

In terms of clinical applications previous studies have identified that the psychological needs of prostate cancer patients are often unmet [30]. The current study has started to identify certain factors that may be linked to psychological distress and sexual dysfunction in prostate cancer patients. The

finding that depression, but not anxiety, is related to sexual problems may help clinicians to identify men who are likely to need input. Further research into levels of anxiety, depression and sexual dysfunction at different stages of prostate cancer diagnosis and treatment would help to identify when men are most 'at risk' of low mood and when input would be most valuable.

Looking at other factors associated with psychological distress in prostate cancer patients such as; coping, illness perceptions, and health-related quality of life, has revealed a number of dimensions that appear to be related to higher levels of depression. Assessing for particular styles of coping and perceptions of illness may assist clinicians in identifying patients who may be more 'at risk' of high levels depression and allow them to intervene at an early stage in the cancer treatment process.

The issue of sexual functioning is still somewhat 'taboo' and clinicians reported that many men did not seem comfortable to discuss this issue during appointments. Anecdotal reports revealed that many clinicians also did not often discuss sexual functioning or psychological distress in follow-up appointments with patients. It is hoped that the current study will help to raise awareness of the issues faced by prostate cancer patients and encourage clinicians to ask routinely about sexual functioning and psychological distress in consultations.



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**Table 1 – Demographic data for sample (n=52) including mean age, age range, ethnic background, relationship status, education and employment status**

		<b>Range</b>	<b>Mean</b>
<b>Age:</b>		57-86	70.65
	65 years of age or less	25%	
	66 to 75	48.1%	
	76 years of age or more	26.9%	
<b>Ethnic Background:</b>	White/Caucasian	96.2%	
	Black/African-American	1.9%	
	Asian/Pacific Islander	1.9%	
<b>Relationship:</b>	Living with spouse/partner	86.5%	
	In relationship, not living together	1.9%	
	Not in relationship	11.5%	
<b>Education:</b>	Grade School or less	15.4%	
	Some High/Technical School	26.9%	
	High/Technical School Graduate	13.5%	
	Some College	11.5%	
	College Graduate	7.7%	
	Graduate/Professional School after College	25%	
<b>Employment:</b>	Yes, full-time	9.6%	
	Yes, part-time	7.7%	
	No, looking for a job	1.9%	
	No, retired	78.8%	
	No, disabled	1.9%	

**Table 2 – Summary statistics including mean, standard deviation and range for outcome measures; ASEX, HADS, COPE-B, IPQ-R, SF-36 and UCLA PCI**

		<b>Mean</b>	<b>SD</b>	<b>Range</b>
<b>1) ASEX</b>		24.21	5.65	12-30
<b>2) HADS</b>	Anxiety	5.23	4.32	0-18
	Depression	3.50	3.39	0-13
<b>3) COPE-B</b>	Self distraction	4.02	2.07	2-8
	Active coping	4.77	1.97	2-8
	Denial	2.62	1.22	2-7
	Substance use	2.50	1.26	2-8
	Use of emotional support	5.02	2.17	2-8
	Use of instrumental support	3.60	1.82	2-8
	Behavioural disengagement	2.92	1.43	2-7
	Venting	3.37	1.46	2-7
	Positive reframing	4.31	1.71	2-8
	Planning	4.29	2.02	2-8
	Humour	3.96	2.04	2-8
	Acceptance	5.98	2.01	2-8
	Religion	4.00	2.36	2-8
	Self blame	3.15	1.60	2-8
<b>4) IPQ-R</b>	Identity	2.04	2.81	0-10
	Timeline (acute/chronic)	22.00	5.16	8-30
	Consequences	18.04	4.54	10-26
	Personal control	17.35	3.61	7-25
	Treatment control	17.35	2.79	11-23
	Illness coherence	17.58	4.13	10-25
	Timeline cyclical	8.88	3.84	4-19
	Emotional representations	15.79	4.70	6-26
	Causes	38.58	8.56	20-56
<b>5) RAND SF-36</b>	Physical functioning	71.54	25.39	0-100
	Role limitations (physical)	62.26	33.51	0-100
	Role limitations (emotional)	74.45	26.27	16.67-100
	Vitality	53.97	27.37	0-100
	Mental health	75.58	17.28	25-100
	Social functioning	77.16	27.42	0-100
	Bodily pain	71.97	29.55	0-100
	General health	60.05	21.47	15-95
	Health Transition	46.63	25.26	0-100
<b>6) UCLA PCI</b>	Urinary function	78.80	24.24	11.60-100
	Bowel function	83.21	20.50	23.75-100
	Sexual function	20.14	24.59	0-96.88
	Urinary bother	75.48	28.65	0-100
	Bowel bother	78.37	31.71	0-100
	Sexual bother	46.63	40.53	0-100

**Table 3 – Means, standard deviations and ranges for measures of anxiety, depression and sexual dysfunction for three age groups; 65 or less, 66 to 75 and 76 plus**

		Mean	SD	Range
<b><u>65 or less</u></b>				
N=13				
1) ASEX		22.0	6.11	14-30
2) HADS	Anxiety	5.85	5.19	0-16
	Below cut off (7 or less)	61.54%		
	Above cut off (8+)	38.46%		
	Depression	3.62	3.45	0-10
	Below cut off (7 or less)	84.62%		
	Above cut off (8+)	15.38%		
3) UCLA PCI	Sexual function	26.52	28.33	0-78.13
	Sexual bother	26.92	34.55	0-100
<b><u>66 - 75</u></b>				
N=25				
1) ASEX		23.36	5.79	12-30
2) HADS	Anxiety	4.64	3.50	0-13
	Below cut off (7 or less)	84%		
	Above cut off (8+)	16%		
	Depression	2.68	3.16	0-12
	Below cut off (7 or less)	92%		
	Above cut off (8+)	8%		
3) UCLA PCI	Sexual function	24.05	26.05	0-96.88
	Sexual bother	54.00	38.65	0-100
<b><u>76 plus</u></b>				
N=14				
1) ASEX		27.79	3.02	20-30
2) HADS	Anxiety	5.71	4.95	0-18
	Below cut off (7 or less)	78.57%		
	Above cut off (8+)	21.43%		
	Depression	4.86	3.53	0-13
	Below cut off (7 or less)	85.71%		
	Above cut off (8+)	14.29%		
3) UCLA PCI	Sexual function	7.22	11.38	0-38.50
	Sexual bother	51.79	45.43	0-100



## **Chapter 5: Single Case Research Proposal**

**An Experimental Analysis Of Self-Injurious Behaviour In An Individual With A  
Moderate Intellectual Disability.**

**(Part Two bound separately)**

**Prepared in accordance with guidelines for 'single case research proposal' in  
Doctorate of Clinical Psychology Research Training Folder**

**Rebecca Clifford  
Section of Psychological Medicine  
University of Glasgow  
Division of Community Based Sciences  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH**

**Submitted in partial fulfilment of the requirements of the degree of Doctorate in  
Clinical Psychology**

## **Title**

An Experimental Analysis Of Self-Injurious Behaviour In An Individual With A Moderate Intellectual Disability.

## **Abstract**

This study aimed to look at the relationship between certain ecologically valid situations and self-injurious behaviour in an individual with a moderate intellectual disability. Challenging behaviour has been identified as an ongoing issue for carers and service providers for people with intellectual disabilities, with between 10 and 15% of people with intellectual disabilities displaying some form of challenging behaviour (Emerson, 1998). Tasse (2006) stated that understanding the function of challenging behaviour was a critical component to developing an effective intervention plan. Following on from these recommendations a baseline assessment of the case was completed with a view to investigating the context of the self-injurious behaviour. The participant's most frequent form of self-injurious behaviour was face punching, therefore, the study was designed to focus on situations when this behaviour occurred. From baseline information it appeared that the individuals' self-injurious behaviour was less frequent in certain situations, for example, when sitting alone. Following the completion of a baseline assessment an experimental analysis of behaviour was carried proposed involving four ecologically valid conditions: alone, with staff, with other residents, with staff and residents. The findings of the baseline assessment are discussed, along with methods and for the proposed experimental analysis. Possible applications for findings of the experimental analysis are also discussed.

## Appendices

### Appendix 1 – Small Scale Service Related Project

#### Appendix 1.1 - An Audit of the Evening Clinics running in the East Area of Glasgow Clinical Psychology Service: A Management Presentation

An Audit of the Clinical  
Psychology Evening Clinics  
running in the East of Glasgow

**A Management Report**

#### **Background**

- Clinical Psychology Waiting List
- Review - Audit Scotland (2002)
- Managing Waiting Times: Good Practice Guide - Scottish Executive (2003)

#### **Audit Questions**

- How many appointments were available?
- How many new people were seen?
- How many appointments were taken up?
- How many people attended?

#### **Audit Questions**

- How many times did people attend?
- How many people were discharged?
- How many people were offered day-time sessions?
- What was the immediate impact on the waiting list?

### **Method**

- Sample – 224 patients
- Waiting List Initiative Database
- Patient Information Management System
- Descriptive Statistics

### **Results**

- 242 new patients taken off waiting list
- 56% Attended
- 22% DNA
- 15% Cancelled
- Day-time Service: 64% Attended  
23% DNA  
13% Cancelled

### **Results**

- 29% discharged after clinics
- 33% offered further input
- 3% reduction in waiting list after 1<sup>st</sup> clinic
- 15% reduction in waiting list after 2<sup>nd</sup> clinic

### **Conclusions & Recommendations**

- Small reduction in number of people on waiting list after each clinic
- Further investigation of factors impacting upon waiting list
- Consider alternative uses of evening clinics

## Appendix 2 – Systematic Literature Review

### Appendix 2.1 – Notes to Authors for Psycho-Oncology

#### Manuscript Submission

**All papers must be submitted via the online system.**

*Psycho-Oncology* operates an online submission and peer review system that allows authors to submit articles online and track their progress via a web interface.

Please read the remainder of these instructions to authors and then click <http://mc.manuscriptcentral.com/pon> to navigate to the *Psycho-Oncology* online submission site. **IMPORTANT:** Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the journal in the past year it is likely that you will have had an account created.

**File types.** Preferred formats for the text and tables of your manuscript are .doc, .rtf, .ppt, .xls. **LaTeX** files may be submitted provided that an .eps or .pdf file is provided **in addition** to the source files. Figures may be provided in .tiff or .eps format.

**Please note:** This journal does not accept Microsoft Word 2007 documents at this time. Please use Word's "Save As" option to save your document as a .doc file type. If you try to upload a Word 2007 document in Manuscript Central you will be prompted to save .docx files as **.doc** files.

#### Initial Submission

**Non-LaTeX Users:** Upload your manuscript files. At this stage, further source files do not need to be uploaded.

**LaTeX Users:** For reviewing purposes you should upload a single .pdf that you have generated from your source files. You must use the File Designation "Main Document" from the dropdown box.

#### Revision Submission

**Non-LaTeX Users:** Editable source files must be uploaded at this stage. Tables must be on separate pages after the reference list, and not be incorporated into the main text. Figures should be uploaded as separate figure files.

**LaTeX Users:** When submitting your revision you must still upload a single .pdf that you have generated from your now revised source files. You must use the File Designation "Main Document" from the dropdown box. In addition you must upload your TeX source files. For all your source files you must use the File Designation "Supplemental Material not for review". Previous versions of uploaded documents must be deleted. If your manuscript is accepted for publication we will use the files you upload to typeset your article within a totally digital workflow.

#### Copyright and Permissions

Authors **must** sign, scan and upload to the online system:

- a Copyright Transfer Agreement with original signature(s) - without this we are unable to accept the submission, and
- permission grants - if the manuscript contains extracts, including illustrations, from other copyright works (including material from on-line or intranet sources) it is the author's responsibility to obtain written permission from the owners of the publishing rights to reproduce such extracts using the Wiley Permission Request Form.

The Copyright Transfer Form and the Permissions Form should be uploaded as "Supplementary files not for review" with the online submission of your article.

If you do not have access to a scanner, further instructions will be given to you after acceptance of the manuscript.

To enable the publisher to disseminate the author's work to the fullest extent, the author must sign a Copyright Transfer Agreement, transferring copyright in the article from the author to the publisher, and submit the original signed agreement with the article presented for publication. A copy of the agreement to be used (which may be photocopied) can be found in the first issue of the year on the *Wiley InterScience* website and through links in the online submission system. Copies may also be obtained from the journal editors or publisher.

Submission of a manuscript will be held to imply that it contains original unpublished work and is not being submitted for publication elsewhere at the same time. Submitted material will not be returned to the author, unless specifically requested.

**Manuscript style.** The language of the journal is English. 12-point type in one of the standard fonts: Times, Helvetica, or Courier is preferred. It is not necessary to double-line space your manuscript. Tables must be on separate pages after the reference list, and not be incorporated into the main text. Figures should be uploaded as separate figure files.

- During the submission process you must enter the full title, short title of up to 70 characters and names and affiliations of all authors. Give the full address, including email, telephone and fax, of the author who is to check the proofs.
- Include the name(s) of any **sponsor(s)** of the research contained in the paper, along with **grant number(s)**.
- Enter an **abstract** of up to 250 words for all articles. An abstract is a concise summary of the whole paper, not just the conclusions, and is understandable without reference to the rest of the paper. It should contain no citation to other published work.
- Include up to six **keywords** which **must** contain the words cancer and oncology that describe your paper for indexing purposes.
- Research Articles should not exceed 4500 words (including figures and/or tables but excluding references). The limit for Brief Reports is 2000 words including no more than two tables or figures and no more than 20 references.

All abbreviations except for SI symbols should be written in full the first time they appear. Generic or clinical names should be used for all compounds: materials and products should be identified. The species of any animals used should be stated precisely. Sources of unusual materials and chemicals, and the manufacturer and model of equipment should be indicated. materials and products should be identified in the text followed by the trade name in brackets.

**Reference style.** References should be cited in the text by number within square brackets and listed at the end of the paper in the order in which they appear in the text. All references must be complete and accurate. If necessary, cite unpublished or personal work in the text but do not include it in the reference list. Where possible the [DOI](#) for the reference should be included at the end of the reference. Online citations should include date of access. References should be listed in the following style:

1. Decker, CL. Social support and adolescent cancer survivors: A review of the literature. *Psycho-Oncol* 2007; **16**: 1-11.
2. Peterson AC, Leffert N. What is special about adolescence? In *Psychosocial Disturbances in Young People: Challenges for Prevention*, Rutter M (ed.).Cambridge University Press: Cambridge, 1997;3-36.

**Illustrations.** Upload each figure as a separate file in either .tiff or .eps format, with the figure number and the top of the figure indicated. Compound figures e.g. 1a, b, c should be uploaded as one figure. Tints are not acceptable. Lettering must be of a reasonable size that would still be clearly legible upon reduction, and consistent within each figure and set of figures. Where a key to symbols is required, please include this in the artwork itself, not in the figure legend. All illustrations must be supplied at the correct resolution:

- Black and white and colour photos - 300 dpi
- Graphs, drawings, etc - 800 dpi preferred; 600 dpi minimum
- Combinations of photos and drawings (black and white and colour) - 500 dpi

Tables should be part of the the main document and should be placed after the references. If the table is created in excel the file should be uploaded separately.

**Colour Policy.** Where colour is necessary to the understanding of the figures, colour illustrations will be reproduced in the journal without charge to the author, at the Editor's discretion.

### **Post Acceptance**

**Further Information.** For accepted manuscripts the publisher will supply proofs to the submitting author prior to publication. This stage is to be used only to correct errors that may have been introduced during the production process. Prompt return of the corrected proofs, preferably within two days of receipt, will minimise the risk of the paper being held over to a later issue. Twenty-five complimentary offprints will be provided to the author who checked the proofs, unless otherwise indicated. Further offprints and copies of the journal may be ordered. There is no page charge to authors.

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If so, check out our suite of tools and services for [authors](#) and sign up for:

- Article Tracking
- E-mail Publication Alerts
- Personalization Tools

### **Cite EarlyView Articles**

To link to an article from the author's homepage, take the DOI (digital object identifier) and append it to "http://dx.doi.org/" as per following example:

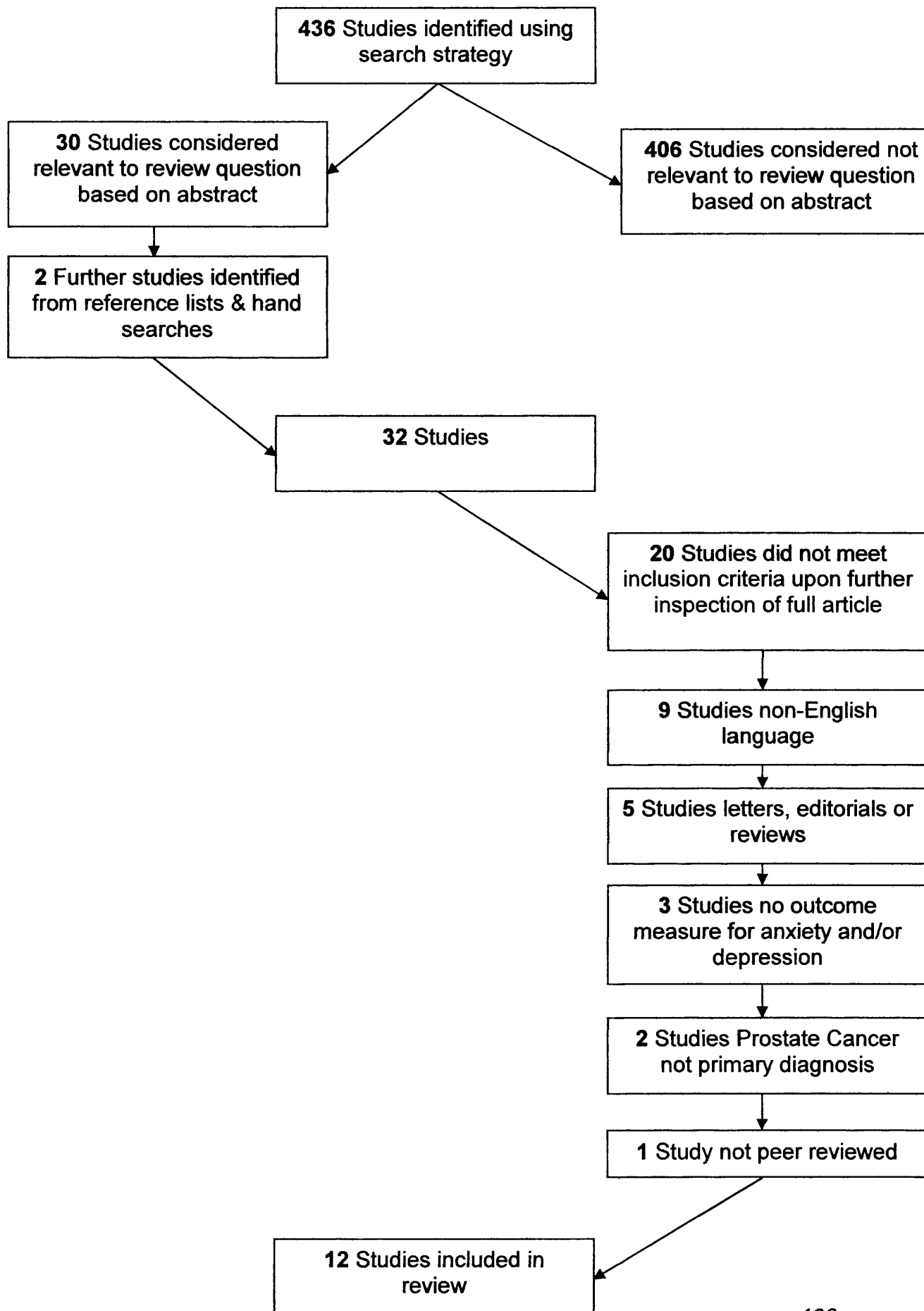
DOI 10.1002/hep.20941, becomes <http://dx.doi.org/10.1002/hep.20941>.

To include the DOI in a citation to an article, simply append it to the reference as in the following example:

Oestreicher, N., The cost of adjuvant chemotherapy in patients with early-stage breast carcinoma, *Cancer* **10(1)**, pp. 2054 - 2062, DOI: 10.1002/cncr.21464.



## Appendix 2.2 - Study Flowchart



## Appendix 2.3 - Methodological Checklist

<b>Author</b>	
<b>Year</b>	
<b>Title</b>	

<b>1 - Introduction</b>		<b>Not Addressed, Not reported or Not applicable</b>	<b>Poorly Addressed</b>	<b>Well Covered or Adequately Addressed</b>
1.1 Study addresses appropriate & clearly focused question		0	1	2
1.2 Study has clearly stated aims		0	1	2
1.3 Study has clearly stated hypotheses		0	1	2
<b>2 - Participants</b>				
2.1 Clearly defined study population		0	1	2
2.2 Sample size stated		0	1	2
2.3 Sample demographics stated		0	1	2
2.4 Power calculation to justify sample size		0	1	2
2.5 Control group		0	1	2
2.6 Cases & controls taken from		0	1	2

comparable populations				
2.7 Assignment to treatment groups is randomised		0	1	2
2.8 Inclusion criteria stated		0	1	2
2.9 Exclusion criteria stated		0	1	2
2.10 Study indicates how many people asked to take part did so		0	1	2
2.11 Study states how many people dropped out before study was completed		0	1	2
<b>3 - Procedures</b>				
3.1 Outcome measures clearly defined		0	1	2
3.2 All relevant outcomes are measured in a standard, valid & reliable way		0	1	2
3.3 Evidence from other sources is used to demonstrate that the method of outcome assessment is valid & reliable		0	1	2
3.4 If non-standardised measures, measure described, and		0	1	2

reliability & validity stated				
<b>4 – Results &amp; Analysis</b>				
4.1 Results clearly stated		0	1	2
4.2 Appropriate statistical tests used		0	1	2
4.3 All participants are analysed in the groups		0	1	2
4.4 Where study is carried out at multiple sites results are comparable for all sites		0	1	2
4.5 Confidence intervals have been provided		0	1	2
4.6 Main potential confounders are identified & taken into account in the design & analysis		0	1	2
<b>Score (Out of 48)</b>				

## Appendix 3 – Major Research Project Proposal

### Appendix 3.1 – IHTAB ethics confirmation

Postgraduate Research Student

Page 1 of 1

**From:** Andrea Harkin  
**To:** 0403467C@student.gla.ac.uk  
**Cc:**  
**Date:** 12/20/06 05:28 pm  
**Subject:** Re: IHTAB  
**Attachments:**

Hi Rebecca

I can confirm that your proposal was discussed at our recent IHTAB meeting on 14th November 2006 and that this was approved. No support was required from the Clinical Trials Unit.

Best of luck with your application.

Kind regards

Andrea

Andrea Harkin  
Head of Trial Co-ordination  
Cancer Research UK Clinical Trials Unit, Glasgow  
(partner in CaCTUS - Cancer Clinical Trials Unit Scotland)  
38 Church Street  
1st Floor E Block  
Western Infirmary  
Glasgow G11 6NT

Tel: 0141 211 8558  
Fax: 0141 211 6239  
<http://www.crukctuglasgow.org>

## Appendix 4 – Major Research Project

### Appendix 4.1 – Glasgow West Local Research Ethics Committee letter

North Glasgow University Hospitals  
Division

**NHS**  
  
**Greater  
Glasgow**  
**West Glasgow Ethics Committee 2**  
Western Infirmary  
Dumbarton Road  
Glasgow  
G11 6NT  
Telephone: 0141 211 6238  
Facsimile: 0141 211 1920

20 February 2007

Miss R Clifford  
Trainee Clinical Psychologist  
Section of Psychological Medicine  
Division of Community Based Sciences  
Gartnavel Royal Hospital  
1055 Great Western Road, Glasgow  
G12 0XH

Dear Miss Clifford

**Full title of study:** Life After Treatment for Prostate Cancer: Levels of  
Anxiety, Depression, and Sexual Dysfunction.  
**REC reference number:** 06/S0709/145

The Research Ethics Committee reviewed the above amended application at the meeting held on 20 February 2007.

#### **Ethical opinion**

The Committee reviewed the amendments contained within your letter dated 10th January, 2007 and approved these.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

#### **Ethical review of research sites**

The favourable opinion applies to the research sites listed on the attached form.

#### **Conditions of approval**

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

#### **Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Application	5.2	23 November 2006
Investigator CV		01 November 2006
Protocol	1.4	23 November 2006
Covering Letter		23 November 2006
Covering Letter		10 January 2007
Questionnaire		08 January 2007
Participant Information Sheet	1.0	23 November 2006
Participant Information Sheet	1	23 November 2006
Participant Consent Form	1	23 November 2006
Participant Consent Form	1.0	23 November 2006
Response to Request for Further Information		10 January 2007
Letter from Dr S Porteous Field Supervisor		12 January 2007
Summary CV for supervisor		23 November 2006

### Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

### Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

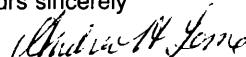
### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

<b>06/S0709/145</b>	<b>Please quote this number on all correspondence</b>
---------------------	---

With the Committee's best wishes for the success of this project

Yours sincerely



**Andrea H Torrie**  
**Ethics Manager – West Glasgow LRECs**

Email: andrea.torrie@northglasgow.scot.nhs.uk

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments  
Standard approval conditions SL-AC2  
Site approval form (SF1)*

*Copy to: Mr Brian Rae  
NHS Greater Glasgow and Clyde Research and Development  
Directorate  
Research and Development Directorate*



**UNIVERSITY  
of  
GLASGOW**

**Title:** Life After Treatment for Prostate Cancer: Levels of Anxiety, Depression, and Sexual Dysfunction.

We would like to invite you to take part in a research study. We are interested in learning about your experiences of life after being diagnosed with and treated for Prostate Cancer. You have been given this pack as you may be able to help us in this study. My name is Rebecca Clifford, I am a Trainee Clinical Psychologist and I will be running the study. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve. Please read this information carefully.

**What is the research about?**

We are interested in understanding your experiences of life after being treated for prostate cancer. In particular: your mood, how you have coped, if your sexual functioning has changed, what you think about your illness, and your quality of life. We are also interested in how all of these things are related to each other.

This kind of research is important in developing a better understanding of the psychological needs of men with prostate cancer. The study will be run from November 2006 to June 2007.

**Why have I been asked to take part?**

We are asking men who have been diagnosed with and treated for prostate cancer to participate in this study. A total of approximately 80 men are being asked to take part.

**Do I have to take part?**

You do not have to take part in this study. If you decide to take part you will be asked to sign a consent form. The consent form is a way of making sure you know what you have agreed to. If you decide to take part you are still free to withdraw from the study at any time and you do not have to give a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What do I have to do?**

If you would like to take part please complete the two consent forms and seal them in the separate consent form envelope. One consent form will be kept on file and the other will be sent back to you. Next complete the five questionnaires in this pack. Put all of the completed forms into the stamped addressed envelope in your pack and post it to Gartnavel Royal Hospital. Please put your hospital number on top of each questionnaire, **NOT** your name.

PSYCHOLOGICAL MEDICINE

Division of Community Based Sciences

Academic Centre, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12 0XH

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*Head of Section of Psychological Medicine: Dr Elizabeth A Campbell*



**What is the downside?**

It is possible that the questionnaires may cover topics that are difficult or distressing for you to think about. If you report high levels of anxiety or depression in the questionnaires your Clinical Nurse Specialist and Consultant will be notified.

**What are the possible benefits of taking part?**

The information we learn from the study will help us plan future research and develop psychological services for men with prostate cancer. If you are experiencing high levels of distress this research will allow you to access appropriate additional services should you wish to.

**Will my taking part in this study be kept confidential?**

You have written your hospital number on top of each questionnaire, not your name. Your participation in this study will be kept confidential. The only time when this would not be the case is if you reported high levels of distress, when your Clinical Nurse Specialist and Consultant would be informed.

**What will happen to the results of the research study?**

Your Consultant and Clinical Nurse Specialist will have a summary of the results of the study for you to read should you wish. The final results and conclusions of the study will be published in a scientific journal and will form part of my qualification in Clinical Psychology. Your identification will not be included in any publication.

**Who is organising and funding the research?**

The University of Glasgow.

**Who has reviewed the study?**

The study has been reviewed by the Department of Psychological Medicine to ensure that it meets standards of scientific conduct and has been reviewed by NHS Greater Glasgow Research Ethics Committee to ensure that it meets standards of ethical conduct.

**Contact Details**

If you have any queries please speak to your Consultant, your Clinical Nurse Specialist or myself using the details below.

Name – Rebecca Clifford, Trainee Clinical Psychologist

Telephone – 0141 211 0607

E-mail – 0403467c@student.gla.ac.uk

**Thank you very much for reading this and for any further involvement you may have with the study.**

## Appendix 4.3 - Consent Form

**Title of Project:** Rebecca Clifford's Research Project

**Name of Researcher:** Rebecca Clifford

**Patient Hospital Number:** .....



**UNIVERSITY  
of  
GLASGOW**

**Please tick box**

1. I confirm that I have read and understood the information sheet for the above study.

☐

1. I understand that my participation is voluntary and I am free to withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.

☐

1. If I report significant levels of anxiety or depression I understand that my Clinical Nurse Specialist, and Consultant will be informed

☐

1. I agree to take part in the above study

☐

Print Name .....

Signature .....

Date .....

Address .....

.....

**Please sign both consent forms and send them back separately in the small envelope in your pack. Thank you.**

## Appendix 4.4 – Arizona Sexual Experiences Scale (ASEX)

HOSPITAL NUMBER .....

### ARIZONA SEXUAL EXPERIENCES SCALE (ASEX)-MALE

For each item, please indicate your **OVERALL** level during the **PAST WEEK**, including **TODAY**.

1. How strong is your sex drive?

1	2	3	4	5	6
extremely strong	very strong	somewhat strong	somewhat weak	very weak	no sex drive

2. How easily are you sexually aroused (turned on)?

1	2	3	4	5	6
extremely easily	very easily	somewhat easily	somewhat difficult	very difficult	never aroused

3. Can you easily get and keep an erection?

1	2	3	4	5	6
extremely easily	very easily	somewhat easily	somewhat difficult	very difficult	never

4. How easily can you reach an orgasm?

1	2	3	4	5	6
extremely easily	very easily	somewhat easily	somewhat difficult	very difficult	never reach orgasm

5. Are your orgasms satisfying?

1	2	3	4	5	6
extremely satisfying	very satisfying	somewhat satisfying	somewhat unsatisfying	very unsatisfying	can't reach orgasm

COMMENTS:



**UNIVERSITY  
of  
GLASGOW**

**Life After Treatment for Prostate Cancer: Levels of Anxiety, Depression,  
and Sexual Dysfunction.**

Dear Sir,

Thank you very much for taking part in the above research study.

Please find enclosed the counter signed consent form for your reference.

You do not need to take any further action regarding this study.

We wanted to know about your experiences of life after being treated for prostate cancer.

In particular: your mood, how you have coped, if your sexual functioning has changed, what you think about your illness, and your quality of life. We also wanted to know how all of these things were related to each other.

Your answers will help us to develop a better understanding of the psychological needs of men with prostate cancer. The information we learn from this study will help us plan future research and develop psychological services for men with prostate cancer.

Your Consultant and Clinical Nurse Specialist will have a summary of the results of the study for you to read should you wish. This summary will be available in December 2007.

**Thank you very much for taking part.**

PSYCHOLOGICAL MEDICINE  
Division of Community Based Sciences

Academic Centre, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12 0XH

*Head of Section of Psychological Medicine: Dr Elizabeth A Campbell*

